

# NAVY

## MEDICAL AND DENTAL MATERIEL

### BULLETIN



#### SUGGESTED ROUTING:

##### SHIPS:

Senior Medical Dept. Rep. \_\_\_\_\_  
Senior Dental Dept. Rep. \_\_\_\_\_  
Medical Dept. Supply LPO \_\_\_\_\_  
Dental Dept. Supply LPO \_\_\_\_\_  
Supply Officer \_\_\_\_\_

##### FLEET MARINE FORCE:

MAW Surgeon \_\_\_\_\_  
Division Surgeon \_\_\_\_\_  
Group Surgeon \_\_\_\_\_  
Medical/Dental Battalion \_\_\_\_\_  
FSSG (MEDLOGCO) \_\_\_\_\_  
RAS \_\_\_\_\_  
BAS \_\_\_\_\_

##### BUMED MTFs/DTFs:

Materiel Management \_\_\_\_\_  
Equipment Manager \_\_\_\_\_  
BioMedical/Dental Engineering \_\_\_\_\_  
CORs \_\_\_\_\_  
Central Processing Dept. \_\_\_\_\_  
Pharmacy \_\_\_\_\_  
Laboratory \_\_\_\_\_  
Comptroller/Fiscal Officer \_\_\_\_\_  
Legal Officer \_\_\_\_\_  
Safety \_\_\_\_\_  
Branch Clinics (Supply) \_\_\_\_\_

**NAVAL MEDICAL LOGISTICS COMMAND**  
**521 FRAIM STREET**  
**FORT DETRICK MD 21702-5015**

**10-97**

**NAVAL MEDICAL LOGISTICS COMMAND  
521 FRAM STREET  
FORT DETRICK MD 21702-5015**

|  |      |                                |          |
|--|------|--------------------------------|----------|
| <b>COMMANDING OFFICER</b>                                    | 00   | CAPT T. R. DEFIBAUGH, MSC, USN | 619-2157 |
| Secretary  | 00S  | MRS. G. Y. VANSANT             | 619-2157 |
| Command Master Chief   | 00C  | HMCM(NAC) K. P. BRANNIGAN, USN | 619-3076 |
| Command Counsel  | 00L  | MR. J. R. OSING, JR.           | 619-2157 |
| <b>EXECUTIVE OFFICER</b>                                     | 09   | CDR T. L. TATMAN, MSC, USN     | 619-2157 |
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| Support Services Division                                    | 11   | HMC C. T. SIMMONS, USN         | 619-7169 |
| Management Information Division                              | 12   | LT L. M. OWENS, MSC, USN       | 619-7168 |
| Publication Division   | 13   | MRS. R. M. CRESPO              | 619-3115 |
| Training Division  | 14   | DT1 V. M. FAVELA, USN          | 619-3114 |
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| Assistant Head   | 02A  | LT G. J. BAKER, SC, USN        | 619-3069 |
| Contingency Programs Division                                | 21   | VACANT                         | 619-7220 |
| Equipment and Outfitting Division                            | 22   | HMCM(NAC) K. P. BRANNIGAN, USN | 619-3076 |
| <b>HEAD, EQUIPMENT SUPPORT DEPARTMENT</b>                    | 03   | LCDR D. B. STRATTON, MSC, USN  | 619-7247 |
| Assistant Head   | 03A  | LT R. R. OWENS, MSC, USN       | 619-3009 |
| Asset Management Division                                    | 31   | LT R. R. OWENS, MSC, USN       | 619-3009 |
| Equipment Management   | 31-4 | MRS. J. L. DANIS               | 619-3080 |
| Excess Equipment Redistribution                              | 31-5 | MRS. D. K. MILLER              | 619-3082 |
| Procurement Support Division                                 | 32   | VACANT                         | 619-7110 |
| Biomedical Engineer  | 32   | MR. F. L. BOALS                | 619-3063 |
| <b>HEAD, FINANCIAL MANAGEMENT DEPARTMENT</b>                 | 04   | LT R. C. BARRIEAULT, MSC, USN  | 619-7558 |
| Accounting Division  | 41   | MR. R. L. ROUTZAHN             | 619-3391 |
| Budget Division  | 42   | MS. N. F. NEEL                 | 619-3390 |
| Receipt Control Division                                     | 43   | MRS. J. T. LIPELLA             | 619-3393 |
| <b>HEAD, ACQUISITION MANAGEMENT DEPARTMENT</b>               | 05   | MRS. T. T. DELMONICO           | 619-3015 |
| Contracts Division 1   | 51   | MRS. T. T. DELMONICO           | 619-3013 |
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| Acquisition Support Division                                 | 53   | MRS. Z. C. SHULTZ              | 619-2063 |
| <b>HEAD, MARKETING &amp; CUSTOMER SUPPORT DEPARTMENT</b>     | 06   | LCDR A. M. CAPANO, MSC, USN    | 619-3065 |
| Assistant Head   | 06A  | LTJG A. R. WILLIAMS, MSC, USNR | 619-3086 |
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| Prime Vendor - MEDSURG/Precious Metals Recovery Program Rep. | 622  | VACANT                         | 619-7119 |
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| <b>HEAD, HEALTHCARE SUPPORT DEPARTMENT</b>                   | 07   | LCDR H. N. HOLLEY, MSC, USN    | 619-3089 |
| Division I   | 71   | MR. W. L. FEHLINGER            | 619-3041 |
| Division II  | 72   | MR. A. C. MUENZFELD            | 619-3095 |
| <b>HEAD, BUSINESS AND SUPPORT SYSTEMS TECHNOLOGIES DEPT.</b> | 08   | LCDR W. P. BRADLEY, MSC, USN   | 619-2084 |

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FINANCIAL MANAGEMENT DEPARTMENT: 301-619-7557  
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## DEPARTMENT OF THE NAVY

NAVAL MEDICAL LOGISTICS COMMAND  
FORT DETRICK  
FREDERICK, MARYLAND 21702-5015

IN REPLY REFER TO

Canc: OCTOBER 1998  
NAVMEDLOGCOM NOTE 6700  
Code 13  
01 October 1997

### NAVMEDLOGCOM NOTICE 6700

From: Commanding Officer  
To: Ships and Stations Having Medical and Dental Personnel  
  
Subj: NAVY MEDICAL AND DENTAL MATERIEL BULLETIN

Encl: (1) Navy Medical and Dental Materiel Bulletin  
(NMDMB 10-97)

1. Purpose. To promulgate technical and supply information for the management of medical and dental (Cognizance 9L) materiel held at Navy and Marine Corps activities either in the Navy Stock Account (51000) or in an end use status.
2. Action. Enclosure (1) should be routed for information and appropriate action and should be retained until canceled or as long as required for reference.

  
T. R. DEFIBAUGH

The Navy Medical and Dental Materiel Bulletin (NMDMB) is a specialized bulletin published by the Naval Medical Logistics Command (NMLC). The NMDMB is published monthly to provide timely medical materiel support data to medical activities worldwide. Our mission is to ensure that all medical facilities receive the highest level of medical logistics support. In that regard, we solicit your articles for inclusion in the NMDMB to relay information for use by other activities. For additional information concerning this publication, call (301) 619-3115, DSN 343-3115 or write to the Naval Medical Logistics Command, ATTN: Code 13, 521 Fraim Street, Fort Detrick, Maryland 21702-5015.

The use of a name of any specific manufacturer, commercial product, commodity, or service in this bulletin does not imply endorsement by the Navy.

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## NOTES OF INTEREST AND GUIDANCE

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### FROM THE COMMANDING OFFICER

One of the medical logisticians' targets is to deliver goods and services at the "lowest delivered cost." A simple formula to do this is

*standardization = buying power = lowest prices.*

As we go on with our business practice reengineering I continue to ask, "Now that Prime Vendor is expanding and meeting the needs of our customers, what is next?" The answer is debuting in TRICARE Region 6. While the initial prime vendor efforts tackled overhead costs and improved delivery times for materiel, prime vendor II is tackling price. With the Air Force taking the lead in Region 6, and importantly the Army and Navy supporting this issue, anticipated result is a projected saving of \$8 million of DHP funds. This estimate is based on a 5 percent price reduction in the Air Force alone.

Tactics to do this include collection of consumption data within the region, achieve standardization throughout the region, negotiate regional prices based on current volumes, and establish committed volume contracts. With items such as laboratory consumables not on prime vendor, we estimate \$750K savings in this area alone with a committed volume contract. Also, standardization on packs and gowns can save an additional \$250K.

To make this work, a strong partnership needs to occur between the clinical users, the logisticians, and the manufacturers and suppliers. Our challenge is to make this initiative work, export the tenants to other TRICARE Regions and then figure out how we make this work to support the operating forces. LCDR Tony Capano of my staff can assist you with some tools for you to take a look at your facility. He can be reached at (301) 619-3065, DSN 343-3065, or E-mail: tcapano@nml10.med.navy.mil.

### DMLSS PROGRESS NOTES

#### TECHNOLOGY UPDATE

The **Universal Data Repository (UDR)** will replace the Product and Price Comparison (PPC) tool as the desktop based medical product research tool by October 1997. The UDR is designed for both clinicians and logisticians. The CD-ROM database gives access to detailed, descriptive data and pricing information on pharmaceutical and medical/surgical items that previously could be obtained only through extensive manual search methods. By giving the user a one-stop view of the products in the repository, the UDR facilitates improved business practices. The UDR enables users to conduct item inquiries using common or brand names vice standard nomenclatures. Users received CD-ROM copies of the UDR and PPC disks in their August and September mailings to ease the transition to the new tool. Features of the UDR on CD-ROM include:

- Identification of products by:
  1. Nomenclature

## NOTES OF INTEREST AND GUIDANCE (CONT.)

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2. Part Number
3. NDC Number
4. Manufacturer
5. Catalog Number
6. Prime Vendor Order Number

- Identification of substitute and equivalent items.
- Identification of sources of supply for items with contract and noncontract pricing.
- "Best Price" comparison for selected items.
- Customized customer support information utilizing user-configurable searches.
- Generation of Prime Vendor Item Selection Report from existing local item file.

Sites that have the DMLSS client server Forward Customer Service (FCS) are encouraged to use it for product research vice the UDR. Customers need only log on for access to over 500,000 products including PV, FSS, NSN, and MTF specific items. Prime Vendor order numbers will be added to FCS in a future release.

If you have questions regarding the functionality of the UDR CD-ROM or suggestions for enhancements to better meet your needs, please contact Mr. Bob Franciscovich, UDR Product Manager, who may be reached at (301) 619-7019, by DSN at 343-7019 or by E-mail: [francisr@ftdetreck-ccmail.army.mil](mailto:francisr@ftdetreck-ccmail.army.mil).

### OP PROGRAM

The following depicts OP,DHP funds obligation rates of BUMED activities for the period ending 31 July 1997.

| <u>ACTIVITY</u>  | <u>FY-95</u> | <u>FY-96</u> | <u>FY-97</u> |
|------------------|--------------|--------------|--------------|
| BUMED            | 99%          | -----        | -----        |
| NNMC BETHESDA    | 99%          | 89%          | 92%          |
| NMC PORTSMOUTH   | 97%          | 98%          | 98%          |
| NMC SAN DIEGO    | 99%          | 95%          | 98%          |
| TRICARE          | 99%          | -----        | 25%          |
| NAVMEDLOGCOM     | 99%          | 96%          | 99%          |
| NMIMC BETHESDA   | 99%          | 96%          | 99%          |
| HSO SAN DIEGO    | 99%          | 88%          | 99%          |
| HSO JACKSONVILLE | 99%          | 98%          | 69%          |
| HSO NORFOLK      | 99%          | 99%          | 99%          |
| OVERALL          | 99%          | 96%          | 91%          |
| BUMED            | 0%           | 0.1%         | 3.8%         |
| (UNDISTRIBUTED)  |              |              |              |
| END FY EXPECTED  | 100%         | 95%          | 80%          |

## **NOTES OF INTEREST AND GUIDANCE (CONT.)**

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### **FY-98 NAVAL MEDICAL LOGISTICS CONFERENCE**

The FY-98 Naval Medical Logistics Conference is scheduled for 21-23 April 1998 at the Sheraton Four Points Hotel, Hagerstown, MD. Hagerstown is located approximately 23 miles west of Frederick and 70 miles north of Washington, DC. Further details regarding the conference agenda, theme, and other related topics will be forwarded at a later date.

1998 marks the Tenth Naval Medical Logistics Conference. To honor this occasion, NAVMEDLOGCOM is planning to have commemorative coins made. We are actively seeking suggestions for a design/logo related to Navy Medicine and Navy Medical Logistics.

All suggestions and inputs should be sent to LTJG Anthony Williams who may be reached at (301) 619-3086, by DSN at 343-3086, FAX at (301) 619-3087 or by E-mail: [awilliams@nml10.med.navy.mil](mailto:awilliams@nml10.med.navy.mil).

**William P. Bradley  
Lieutenant Commander, Medical Service Corps  
United States Navy**

Lieutenant Commander Bill Bradley was born in Philadelphia, Pennsylvania on 5 January 1960. He attended and graduated from high school at Our Lady of Providence Preparatory Seminary, Providence, Rhode Island in 1978. He graduated from Boston College, Boston, MA, cum laude with a Bachelor of Science degree in Business Administration in 1982 and from the University of Notre Dame, South Bend, IN with a Masters Degree in Business Administration with honors in 1985. He received his commission as a Lieutenant Junior Grade in the Medical Service Corps in March 1986.

Lieutenant Commander Bradley's previous assignment's include: Assistant Department Head and Department Head, Materiel Management, Naval Hospital, Camp Lejeune, NC; Director for Resources and Logistics, U.S. Naval Medical Clinic, London, UK; Director, Medical Programs, Area ONE, Navy Recruiting, Scotia, NY; Head, Materiel Management, U.S. Naval Hospital, Okinawa, Japan and his current assignment as Department Head, Business and Support Systems Technologies, Naval Medical Logistics Command, Fort Detrick, MD.

Lieutenant Commander Bradley is a graduate of the Navy Medicine Financial and Materiel Management Course. He holds the 1800P, 0031S and 1802S subspecialty codes and Navy Area Recruiting Additional Qualification Designator. He is a Diplomate in the American College of Healthcare Executives.

Lieutenant Commander Bradley's personal decorations include: the Meritorious Service Medal, the Navy Commendation Medal (two awards) and Navy Achievement Medal (three awards).

Lieutenant Commander Bradley is married to the former Kathryn Ann Dascenzo of Youngstown, Ohio. Their children are -- Liam and Cailyn. Lieutenant Commander Bradley and his wife are expecting their third child and live in Gaithersburg, Maryland.

## NOTES OF INTEREST AND GUIDANCE (CONT.)

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### NMLC ESTABLISHES NEW DEPARTMENT

The **Business and Support Systems Technologies Department, (Code 08)** is responsible for coordinating, communicating and representing the Navy Medical Department's logistics input, position and policy pertaining to the Defense Medical Logistics Standard Support System (DMLSS). Acts as Navy Medical Department's logistics representative in all matters pertaining to the integration of all DMLSS-Retail modules into Military Treatment Facilities, and functionally pertinent DMLSS modules into Fleet and Fleet Marine Force Automated Information Systems (AIS). Serves as the Naval Medical Logistics Command's technical information source for all Department of Defense (DoD) AIS with logistics applications. Works closely with NMLC Code 03 to integrate state of the art IM/IT into medical equipment procurements. LCDR Bill Bradley, MSC, USN, CHE is the new Department Head and can be reached at (301) 619-2084 or by e-mail at: [wbradley@nml10.med.navy.mil](mailto:wbradley@nml10.med.navy.mil).

### DON ACQUISITION TRAINING

1. Registration and Cancellation request forms have changed. Request forms follow at the end of this article and can also be accessed on our web server: <http://www-nmlc.med.navy.mil>. When completing the registration form, the following basic guidelines will improve your chances of getting a contracting/purchasing class:
  - a. **Block 2:** The most preferred box to check is "I am available for any session in the quarter requested." This box provides the greatest amount of flexibility for the schedulers.
  - b. **Block 3:** The proper response in this block is NAVMEDLOGCOM. NAVMEDLOGCOM is the acquisition training representative for BUMED.
  - c. **Block 14:** You must occupy an officially designated acquisition position. (See instructions at the end of this article.)
  - d. **Block 15:** If you are a purchasing agent and are requesting purchasing courses, then you can check priority level I or II. If you are a contract specialist and are requesting contracting courses, the same priority applies. However, contract specialists are not required to take purchasing courses and must check priority III. The only exception being if you supervise purchasing agents.
2. All Commands scheduling priority III or IV applicants are required to pay for travel to and from classes.
3. Please complete all blocks on the registration form. Simple omissions such as supervisor code have been cause for not being scheduled. Priority I and II employees will be screened by the training registrar. If you are not in their data base as an acquisition workforce member, you will not be scheduled.



## NOTES OF INTEREST AND GUIDANCE (CONT.)

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4. Defense Acquisition University application cutoff dates are 15 October 1997 for the 2<sup>nd</sup> quarter, 15 January 1998 for the 3<sup>rd</sup> quarter and 15 April 1998 for the 4<sup>th</sup> quarter 1998.
5. If you have completed all the requirements for your particular career field level (1102,1105, etc.) as listed in the Defense Acquisition University Handbook, complete the application for career field certification, also known as Appendix K. Use the instructions listed at the end of this article to complete and submit the application to:

Commanding Officer  
Naval Medical Logistics Command  
Attn: Code 01 (DT1 V. Favela)  
521 Fraim Street  
Fort Detrick, MD 21702-5015

Applications may also be faxed.

6. If there are any questions regarding acquisition training, the NMLC point of contact is DT1 Victor Favela who may be reached at (301) 619-3114, by DSN at 343-3114 or FAX (301) 619-3120.

## **PROCUREMENT MANAGEMENT SUPPORT**

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### **FY-98 APPROPRIATIONS AND FURLOUGH OF CONTRACT PERSONNEL**

Funds for Fiscal Year 1998 (FY-98) are issued subject to the availability of funds (SAF) in anticipation of the enactment of an FY-98 Department of Defense Appropriation Act or an FY-98 Continuing Resolution Authority. Obligations against this sub allocation may not be incurred prior to 1 October 1997 and are subject to all provisions of whichever act becomes applicable. Contracts which begin 1 October 1997 are issued subject to the availability of funds. The SAF clause states, in part, that no legal liability on the part of the Government for any payment may arise until funds are made available to the Contracting Officer for these contracts and until the Contractor receives notice of such availability, to be confirmed in writing by the Contracting Officer.

In the event the Government does not pass a new budget or a continuing resolution authority, it will not continue to operate and only mission essential personnel will be authorized to work.

Government furloughs are not only a hardship on government personnel; but also affect our personal service contractors and customers. In the event a furlough should happen, our personal service contractors should follow the clause in Section C of their contracts entitled "Furlough." This clause informs the customers, the contractors, and the Contracting Officers of their contractual obligations during a Federal Government furlough. It reads as follow:

"Unless otherwise authorized by a defense appropriation's statute, the Government will not reimburse contractors for services not rendered during a government furlough. In the event of a government furlough, the Commanding Officer will determine which contract health care workers are considered critical and therefore must report to work. Contract health care workers deemed critical will be compensated for services rendered during a furlough. All other contract health care workers will be furloughed until the Government shutdown ends or they are notified by the Technical Liaison designated in the contract that they have become critical health care workers."

NMLC point of contact is Ms. Nancy LaVigne who may be reached at (301) 619-3023 or by DSN at 343-3023.

## SHARED PROCUREMENT AWARDS

The Shared Procurement Program provides the customer with state-of-the-art medical equipment at a cost and speed of delivery not obtainable through local contracting activities. To achieve this, DPSC has established long-term Requirements-Type Contracts for specific items of equipment.

Shared procurement of medical equipment has demonstrated significant savings. The Shared Procurement Program also provides technically sound medical equipment, multi-year contracts, standardized products and commercial warranties.

Procurement of any other brand item with a **MANDATORY** contract in effect requires a formal waiver approval from Naval Medical Logistics Command (NMLC).

**NOTE 1:** The Shared Procurement contract awarded to Hewlett-Packard for their model M1722A/B CodeMaster XL+ Defibrillator/Monitor with pacing capabilities for OR, Cardiology and general floor use is a **MANDATORY** contract. The Customer Order List is in the 07-94 issue of the NMDMB, Appendix II. NMLC is the ordering official for this item. Request for Contractual Procurement, NAVCOMPT Form 2276, providing an appropriate line of accounting, shipping address and point of contact along with the COL should be submitted to NMLC, Code 331. **DO NOT SEND DEFIBRILLATOR REQUISITIONS TO DPSC.**

**NOTE 2:** The Zoll Medical Corporation defibrillator and the Protocol Systems Inc. patient physiological monitor contracts were awarded by NMLC. Request for Contractual Procurement, NAVCOMPT Form 2276, providing an appropriate line of accounting, shipping address and point of contact should be submitted to NMLC, Code 331. **DO NOT SEND REQUISITIONS FOR THESE ITEMS TO DPSC.**

**NOTE 3:** The Customer Order Lists (COL) for the Hewlett-Packard , Physio-Control Corporation and Zoll Medical Corporation defibrillators are in the August 1997 issue of the NMDMB, Appendixes I, II, and III.

NMLC point of contact is Mrs. Cheryl Bittner who may be reached at (301) 619-3083, by DSN at 343-3083 or by FAX at (301) 619-2473.

### MANDATORY SHARED PROCUREMENT AWARDS

| <b><u>ITEM</u></b>   | <b><u>NSN</u></b> | <b><u>CONTRACTOR</u></b> | <b><u>CONTRACT PRICE</u></b> | <b><u>CONTRACT NUMBER</u></b> | <b><u>CONTRACT PERIOD</u></b> |
|--|-------------------|--------------------------|------------------------------|-------------------------------|-------------------------------|
| Defibrillator/Monitor<br>with various components<br>MDL: Various | 6515-01-various   | Hewlett-Packard          | \$8,850.99 +                 | DLA12097D8015                 | 03-03-97<br>03-03-02          |

- COL can be found in NMDMB 08-97 Appendix I

## SHARED PROCUREMENT AWARDS (CONT.)

### MANDATORY SHARED PROCUREMENT AWARDS (CONT.)

| <u>ITEM</u>   | <u>NSN</u>  | <u>CONTRACTOR</u>        | <u>CONTRACT PRICE</u> | <u>CONTRACT NUMBER</u> | <u>CONTRACT PERIOD</u> |
|---|---|--------------------------|-----------------------|------------------------|------------------------|
| Defibrillator/Monitor<br>with various components<br>MDL: Various                    | 6515-01-various                                     | Physio-Control           | \$8,498.66 +          | DLA12097D8013          | 03-03-97<br>03-03-02   |
|   | COL can be found in NMDMB 08-97 Appendix II         |                          |                       |                        |                        |
| Defibrillator/Monitor<br>with various components<br>MDL: Various                    | 6515-01-various                                     | Zoll Medical Corporation | \$8,856.10 +          | DLA12097D8012          | 03-03-97<br>03-03-02   |
|   | COL can be found in NMDMB 08-97 Appendix III        |                          |                       |                        |                        |
| Dental Delivery System<br>MDL: Chair-E3000, Unit-AS3000<br>Light-Distinction Series | 6520-(4 NSNs)                                       | Den-Tal-Ez, Inc.         | \$ Various            | SPO20096D8705          | 03-15-96<br>03-14-99   |
|   |   |                          | Surcharge Included    |                        |                        |
|   | -Revised COL can be found in NMDMB 01-97 Appendix I |                          |                       |                        |                        |

## SHARED PROCUREMENT AWARDS (CONT.)

### NONMANDATORY OPTIONAL CONSOLIDATED EQUIPMENT CONTRACTS

These are not mandatory contracts. They are available through DPSC for your use.

| <u>ITEM</u>   | <u>NSN</u>       | <u>CONTRACTOR</u>     | <u>CONTRACT PRICE</u>                     | <u>CONTRACT NUMBER</u> | <u>DATE EXPIRES</u> |
|---|------------------|-----------------------|---|------------------------|---------------------|
| Defibrillator/Monitor/Pacemaker<br>with Shock Advisory<br>External Battery Charger<br>MDL: PD2000 with options  |                  | Zoll Medical Corp.    | \$ 6,300.00<br><br>835.00<br>No Surcharge | N6264595D0086          | 07-31-00            |
| Request for Contractual Procurement, NAVCOMPT Form 2276, providing an appropriate line of accounting, shipping address and point of contact should be submitted to NMLC, Code 331. <u>DO NOT SEND REQUISITIONS FOR THESE ITEMS TO DPSC.</u> |                  |                       |   |                        |                     |
| Electrosurgical Analyzer<br>MDL: 454A   | 6515-01-438-2409 | DNI Nevada            | \$ 5,024.00                               | SPO20097D8702          | 10-01-99            |
| Infant Intensive Care System<br>MDL: IICS-90  | 6515-01-415-7438 | Air Shields Vicker.   | \$14,206.60                               | SPO20095D8707          | 09-26-98            |
| Endoscopic Light<br>MDL: Acuity A09505-G  | 6515-01-435-1572 | TFX Fiberoptics       | \$ 954.00                                 | SPO20096C8532          | 07-30-99            |
| Monitor, Patient Physiological<br>EKG/NIBP/SaO2/2xIBP/Printer<br>Transportable<br>MDL: Propaq 106ELth options   | 6515-01-362-7447 | Protocol Systems Inc. | \$ 6,248.00<br>No Surcharge               | N6264595D0088          | 08-30-00            |

Request for Contractual Procurement, NAVCOMPT Form 2276, providing an appropriate line of accounting, shipping address and point of contact should be submitted to NMLC, Code 331. DO NOT SEND REQUISITIONS FOR THESE ITEMS TO DPSC.

## SHARED PROCUREMENT AWARDS (CONT.)

**NONMANDATORY OPTIONAL CONSOLIDATED EQUIPMENT CONTRACTS (CONT.)**  
**These are not mandatory contracts. They are available through DPSC for your use.**

| <b><u>ITEM</u></b>   | <b><u>NSN</u></b> | <b><u>CONTRACTOR</u></b> | <b><u>CONTRACT PRICE</u></b> | <b><u>CONTRACT NUMBER</u></b> | <b><u>DATE EXPIRES</u></b> |
|--|-------------------|--------------------------|------------------------------|-------------------------------|----------------------------|
| Sterilizer, Surgical Instrument/Dressing<br>MDL: Validator Plus 10 | 6530-01-340-8001  | Pelton and Crane         | \$ 2,448.00                  | SPO20095D8704                 | 04-27-98                   |
| Table, Examination/Power<br>MDL: 111R                              | 6530-01-423-9508  | Midmark Corp.            | \$ 5,325.00                  | SPO20096D8702                 | 09-30-99                   |
| Table, Examination/Treatment<br>MDL: Ritter 100                    | 6530-01-351-9319  | Midmark Corp.            | \$ 671.00                    | SPO20096D8065                 | 07-15-98                   |
| Table, Operating, Manual<br>MDL: 2080M                             | 6530-01-420-7496  | AMSCO                    | \$15,556.00                  | SPO20096D8701                 | 10-26-97                   |
| Table, Operating, Manual<br>MDL: 2080M IA                          | 6530-01-353-9883  | AMSCO                    | \$17,526.00                  | SPO20096C8539                 | 03-24-99                   |
| Table, Overbed, w/Vanity<br>MDL: EO41                              | 6530-01-381-1199  | Joerns Healthcare        | \$ 194.00                    | SPO20096D8701                 | 09-30-98                   |
| Ventilator, Anesthesia<br>MDL: 7000                                | 6515-01-383-0922  | Ohmeda                   | \$ 7,813.00                  | SP020096D8517                 | 02-27-99                   |
| Wheelchair, Folding<br>MDL: MAC 202-100                            | 6530-00-551-4354  | Theradyne                | \$ 198.00                    | SP020096D8028                 | 09-30-99                   |

## **SHARED PROCUREMENT AWARDS (CONT.)**

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+ Denotes accessories at additional cost.

Mandatory Shared Procurement - Add 6.7 percent surcharge to Contract Price to those requisitions forwarded to DPSC only.

NonMandatory Shared Procurement - DPSC surcharge is included in Contract Price.

Customer Order Lists (COL) for NonMandatory items may be obtained from Ms. Anne Harrigan, DPSC-MQ, who may be reached at 215-737-7897, by DSN at 444-7897 or by FAX at 215-737-4113/2079.

Shared Procurement Medical Equipment ordering procedures can be found in NMDMB 12-95 Appendix I.

## **FDA CLASS II AND III RECALLS**

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### **FDA CLASS II RECALLS**

**A class II recall is a situation in which the use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote.**

**PRODUCT**

Clindamycin Phosphate Injection in 2 ml, 4 ml, 6 ml single dose vials and 60 ml and 100 ml bulk pharmacy packages

**RECALL NUMBER**

D-183-7

**CODE**

| SIZE (mL) | RECALLED LOT NUMBER | EXP. DATE                                    |
|-----------|---------------------|--|
| 2a        | P6E007              | 11/97  |
| 4a        | P6E014              | 11/97  |
| 6a        | P6E007F1            | 11/97  |
| 60b       | P6E305*             | 11/97 lot mfg for private label Solopak Labs |
| 60b       | P6K318              | 02/98  |
| 100b      | P6E313              | 11/97  |
| 100b      | P6K320              | 02/98  |

a = Single dose vials    b = Pharmacy bulk package

**MANUFACTURER**

Gensia Laboratories, Irvine, CA

**REASON**

Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA (Abbreviated Antibiotic Drug Application) discrepancies regarding manufacturing process.

**PRODUCT**

Oxygen, USP, Rx compressed medical gas, held in T, K, S, AND, and ANE high pressure cylinders

**RECALL NUMBER**

D-212-7

**CODE**

Lot numbers: E42-7024, E42-7044, E42-7066, E42-7083, E42-7091, E42-7092, E42-7099

**MANUFACTURER**

C.S. Gases, Inc., Buffalo, NY

**REASON**

Failure to properly calibrate finished product testing equipment.

**PRODUCT**

Schein Pharmaceutical Procainamide Hydrochloride Extended-Release Tablets, USP 500 mg, in bottles of 100, indicated for the treatment of documented arrhythmias

**RECALL NUMBER**

D-213-7

**CODE**

Lot Number D6A0204 EXP 2/98

**MANUFACTURER**

Danbury Pharmacal, Danbury, CT

**RECALLED BY**

Danbury Pharmacal, Inc., Caramel, NY

**REASON**

Dissolution failure (stability).



## **FDA CLASS II AND III RECALLS (CONT.)**

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**PRODUCT**

Pentothal (Thiopental Sodium for Injection, USP) Ready-to-Mix Syringe Kit, 500 mg 2.5% (25 mg/ml), used as an anesthetic

**RECALL NUMBER**

D-221-7

**CODE**

Kit Lot Number 26-652-DK

**MANUFACTURER**

Abbott Laboratories, Rocky Mount, NC

**RECALLED BY**

Abbott Laboratories, Hospital Products Division, Abbott Park, IL

**REASON**

Product is packaged in a kit that has a separate expiration date exceeding that of the Pentothal component expiration date.

**PRODUCT**

Clindamycin Phosphate Injection, USP, 150 mg/ml; an Rx small volume parenteral semisynthetic antibiotic for IV or IM administration, packaged in 2 ml, 4 ml, and 6 ml single dose vials and 60 ml bulk vials

**RECALL NUMBER**

D-222-7

**CODE**

List 4050 (2 ml flip-top vial): lots 08-045-DK, 09-055-DK, 11-020-DK, 14-449-DK, 16-537-DK, 20-589-DK

List 4051 (4 ml flip-top vial): lots 07-143-DK, 08-529-DK, 08-541-DK, 08-650-DK, 09-119-DK, 10-537-DK, 12-472-DK, 13-233-DK, 13-258-DK, 15-073-DK, 15-267-DK, 16-606-DK, 18-613-DK, 18-533-DK, 19-223-DK, 20-453-DK, 20-676-DK, 21-188-DK, 22-451-DK, 22-682-DK, 25-023-DK, 26-350-DK List 4052 (6 ml flip-top vial): lots 06-427-DK, 08-383-DK, 09-108-DK, 10-448-DK, 11-293-DK, 13-221-DK, 14-435-DK, 15-135-DK, 16-371-DK, 17-161-DK, 20-381-DK, 22-672-DK List 4053 (2 ml ADD-Vantage vial): lots 15-245-DK, 21-166-DK, 27-276-DK List 4054 (4 ml ADD-Vantage vial): lots 12-417-DK, 13-177-DK, 15-254-DK, 15-264-DK, 16-669-DK, 18-412-DK, 19-198-DK, 19-209-DK, 20-498-DK, 20-509-DK, 21-175-DK, 22-610-DK, 24-531-DK, 25-160-DK, 26-558-DK, 27-002-DK, 27-162-DK List 4055 (6 ml ADD-Vantage vial): 12-427-DK, 13-164-DK, 17-016-DK, 19-220-DK, 20-521-DK, 21-184-DK, 22-600-DK, 25-024-DK, 28-588-DK List 4197 (60 ml): 08-459-DK, 11-250-DK, 18-641-DK, 21-090-DK

**MANUFACTURER**

Abbott Laboratories, Rocky Mount, NC

**RECALLED BY**

Abbott Laboratories, Hospital Products Division, Abbott Park, IL

**REASON**

Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA (Abbreviated Antibiotic Drug Application) discrepancies regarding manufacturing process.

**PRODUCT**

Vicodin Tablets (Hydrocodone Bitartrate 5 mg/Acetaminophen 500 mg), in bottles of 100 tablets, Rx indicated for the relief of moderate to moderately severe pain

**RECALL NUMBER**

D-234-7

**CODE**

7604461 EXP 9/00

**MANUFACTURER**

Knoll Laboratories, A Division of Knoll Pharmaceutical Company, Mount Olive, NJ

**RECALLED BY**

Med-Pro, Inc., Lexington, NE

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **REASON (CONT.)**

Tablet mix-up -- Some bottles of Vicodin were found to contain Trilisate Tablets (Choline magnesium trisalicylate).

### **PRODUCT**

Bio-Safe Antibacterial Lotion (Triclosan 0.3%), OTC, in 8 fluid ounce bottles and 55 gallon drums

### **RECALL NUMBER**

D-236-7

### **CODE**

Lot numbers 6987 (8 ounces) and 7005 (55 gallons)

### **MANUFACTURER**

Stanford Personal Care, Saugus, CA

### **RECALLED BY**

Bio-Safe Skin Products, Milwaukie, OR

### **REASON**

Product is contaminated with *Pseudomonas Aeruginosa*.

### **PRODUCT**

(a) Red Blood Cells; (b) Fresh Frozen Plasma; (c) Cryoprecipitate; (d) Recovered Plasma

### **RECALL NUMBER**

B-856/859-7

### **CODE**

All units collected from 09/1/91 to 11/20/96

### **MANUFACTURER**

NY Blood Services, also known as NY Blood Center, NY

### **REASON**

Blood products may have been improperly tested for viral markers between 09/1/91 and 11/20/96.

### **PRODUCT**

Platelets, Pheresis

### **RECALL NUMBER**

B-887-7

### **CODE**

Unit numbers: 03P98568, 03LL08317, 03LL08316

### **MANUFACTURER**

American Red Cross Blood Services, Atlanta, GA

### **REASON**

Blood products have unacceptable platelet yields.

### **PRODUCT**

(a) Fresh Frozen Plasma; (b) Cryoprecipitate; (c) Recovered Plasma

### **RECALL NUMBER**

B-1023/1025-7

### **CODE**

Units collected on 8/1/96. Contact FDA, Center for Biologics Evaluation and Research, Office of Compliance (301) 594-1191 for individual unit numbers recalled

### **MANUFACTURER**

NY Blood Services, also known as NY Blood Center, NY

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **REASON (CONT.)**

Blood products may been improperly tested (fixed plates) for the antibody to the human immunodeficiency virus type 1 (anti-HIV-1).

### **PRODUCT**

(a) Red Blood Cells; (b) Cryoprecipitated AHF; (c) Plasma; (d) Recovered Plasma

### **RECALL NUMBER**

B-1046/1049-7

### **CODE**

Unit numbers: a) 41FV24002, 41GJ37198, 41GJ37527, 41GW08651, 41GW08967, 41KC09277, 41KC09610; b) 41GJ37198, 41GJ37527; c) 41GJ37527; d) 41FV24002, 41GJ37198, 41GW08651, 41GW08967, 41KC09277, 41KC09610, 41LG53711

### **MANUFACTURER**

American Red Cross Blood Services, Birmingham, AL

### **REASON**

Blood products tested negative for the antibody to the hepatitis C virus encoded antigen (anti-HCV), but were collected from donors who previously tested repeatedly reactive for anti-HCV.

### **PRODUCT**

(a) Fresh Frozen Plasma; (b) Recovered Plasma

### **RECALL NUMBER**

B-1052/1053-7

### **CODE**

|             |         |         |
|-------------|---------|---------|
| (a) 6710747 | 6710751 | 6710753 |
| 6710682     | 6710704 | 6710716 |
| 6710754     | 6710756 | 6710725 |
| 6710701     | 6710709 | 6710722 |
| 6710671     | 6710740 | 6710744 |
| 6710749     | 6710757 | 6710673 |
| 6710686     | 6710695 | 6710724 |
| 6710752     | 6710679 | 6710666 |
| 6710674     | 6710694 | 6710710 |
| 6710681     | 6710718 | 6710720 |
| 6710723     | 6710727 | 6710730 |
| 6710683     | 6710742 | 6710734 |
| 6710739     | 6710670 | 6710729 |
| 6710741     | 6710685 | 6710705 |
| (b) 6710743 | 6710746 | 6710748 |
| 6710755     | 6710693 | 6710668 |
| 6710672     | 6710675 | 6710678 |
| 6710680     | 6710687 | 6710688 |
| 6710689     | 6710690 | 6710731 |
| 6710696     | 6710702 | 6710703 |
| 6710707     | 6710713 | 6710714 |
| 6710715     | 6710717 | 6710721 |
| 6710733     | 6710737 |         |

### **MANUFACTURER**

NY Blood Services, also known as NY Blood Center, NY

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **REASON (CONT.)**

Blood products may have been improperly tested for the antigen to the human immunodeficiency virus type 1 (HIV-1p24 Antigen).

### **PRODUCT**

Red Blood Cells

### **RECALL NUMBER**

B-1075-7

### **CODE**

Unit Number 2028045

### **MANUFACTURER**

Lorain County Blood Bank, Inc., Elyria, OH

### **REASON**

Blood product was incorrectly tested for the antibody to the hepatitis B core antigen (anti-HBc).

### **UPDATE**

### **RECALL NUMBER**

B-886/888-7, Red Blood Cells; Platelets; Plasma, which appeared in the 11 June 1997 Enforcement Report is being rescinded. Information included in this recall is identified as Recall Number B-616/618-6

### **PRODUCT**

Model Number 2800 Portable Ventilator for delivery of gas to patients dependent on artificial respiration

### **RECALL NUMBER**

Z-672-7

### **CODE**

All units

### **MANUFACTURER**

Nellcor Puritan Bennett, Carlsbad, CA

### **REASON**

The High Pressure Alarm does not sound if set a 57 or 60 cm. of water, and the Pressure Relief Valves may stick in the closed position.

### **PRODUCT**

Vangator II Personal Transit Lift, Model Number 9684, an electro-mechanical wheelchair lift for American-made, full-size vans with side doors

### **RECALL NUMBER**

Z-673-7

### **CODE**

Various serial numbers

### **MANUFACTURER**

Crow River Industries, Inc., Brooten, MN

### **RECALLED BY**

Crow River Industries, Inc., Minneapolis, MN

### **REASON**

Part failures allows: (1) the lift platform to free fall from the stowed vertical position to the unstowed horizontal position; and (2) the unfolded lift to drop with the patient on it from the vehicle floor level to the ground surface level.

## FDA CLASS II AND III RECALLS (CONT.)

### PRODUCT

Industrial Laser Products, used for automotive chassis alignment: (a) Model Homer; (b) Model ELVIS

### RECALL NUMBER

Z-676/677-7

### CODE

None

### MANUFACTURER

Romer, Inc., Carlsbad, CA

### REASON

Laser products failed to comply with the Federal laser product performance standard, 21 CFR 1010.2, 1010.3, 1040.10(f)(5), 1040.10(g)(2)(ii), 1040.10(g)(5), and 1040.10(h)(1) in that they lacked certification, identification, emission indicators, warning logotype and aperture labels and user information.

### PRODUCT

A.T.S. reusable Cylindrical Tourniquet Cuffs, used to exert enough pressure on the arterial blood flow within a limb to produce a bloodless operating field: a) DPSB ATS Cuffs; b) SPSB ATS Cuffs; c) DPDB ATS Cuffs; d) SPDB ATS Cuffs

### RECALL NUMBER

Z-679-682-7

### CODE

#### (a) DPSB ATS Cuffs:

| Catalog Number: | Size(in): | Lot Number:  |
|-----------------|-----------|--|
| 60-7500-001-00  | 08        | 91867200, 91825800   |
| 60-7500-002-00  | 12        | 91874800, 91840700, 91811900                               |
| 60-7500-003-00  | 18        | 91880200, 91862800, 91843500, 91830000                     |
| 60-7500-004-00  | 24        | 91859400, 91822900, 91836600, 91889900                     |
| 60-7500-005-00  | 30        | 91894100, 91862900, 91836700                               |
| 60-7500-006-00  | 34        | 91902800, 91900100, 91880300, 91859500, 91836800, 91823600 |
| 60-7500-007-00  | 42        | 91885500, 91863000, 91836900;                              |

#### (b) SPSB ATS Cuffs:

|                |    |  |
|----------------|----|--|
| 60-7600-001-00 | 8  | 91900400, 91837100                     |
| 60-7600-002-00 | 12 | 91885600, 91837200                     |
| 60-7600-003-00 | 18 | 91900500, 91880400, 918455600          |
| 60-7600-004-00 | 24 | 91875000, 91840800                     |
| 60-7600-005-00 | 30 | 91885700                               |
| 60-7600-006-00 | 34 | 91885800, 91867300, 91840900, 91826100 |
| 60-7600-007-00 | 42 | 91885900, 91841000;                    |

#### (c) DPDB ATS Cuffs:

|                |    |                              |
|----------------|----|------------------------------|
| 60-7555-001-00 | 12 | 91872000, 91825900           |
| 60-7555-002-00 | 18 | 91837000, 91874900, 91859600 |
| 60-7555-003-00 | 24 | 91872100, 91855500;          |

#### (d) SPDB ATS Cuffs:

|                |    |                    |
|----------------|----|--------------------|
| 60-7666-002-00 | 18 | 91875100, 91841100 |
| 60-7666-003-00 | 24 | 91867400           |

### MANUFACTURER

Zimmer Patient Care Division, Statesville, NC

### REASON

The cuff has the potential to deflate due to breakage or cracking of the tourniquet port where it is welded to the cuff bladder material.

## **FDA CLASS II AND III RECALLS (CONT.)**

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**PRODUCT**

Vision FX Series Nuclear Imaging System Patient Table

**RECALL NUMBER**

Z-683-7

**CODE**

Serial numbers: 93-96, 100-173, P2, PP3

**MANUFACTURER**

SMV America, Twinsburg, OH

**REASON**

The fasteners used to assemble the motorized patient table were inappropriate for the proper functioning of the device.

**PRODUCT**

Premium Multifire TA (Stapler): (a) Premium Multifire TA 30-V3 (stapler), Order Code 010315; (b) Premium Multifire TA 60-3.5 (stapler), Order Code: 010317; (c) Premium Multifire TA 60-4.8 (stapler), Order Code: 010319

**RECALL NUMBER**

Z-684/686-7

**CODE**

Lot numbers: (a) N6E33, N6E283, N6F91, N6G37, N6H97, N6K55, N6M132, N6M137, N6M232, N6M248, N6G189, N6J06; (b) N6E47, N6E68, N6E303, N6F88, N6F166, N6G88, N6G127, N6H09, N6H84, N6H94, N6H138, N6J19, N6F68, N6J171, N6J217, N6F160, N6K116, N6K186, N6K205, N6M172, N6M269, N7A53, N6F226, N6J186, (c) N6E125, N6F116, N6F178, N6G113, N6H22, N6J30, N6J35F, N6J243, N6K145, N6K175, N6M188, N7A30

**MANUFACTURER**

United States Surgical Corporation, Norwalk, CT

**REASON**

The jaws of the devices may fail to open upon firing a staple, which can result in tissue damage to the patient.

**PRODUCT**

Solar 7000/8000 Patient Monitors with Software Version 4A, used to display physiological data from modules which monitor the patient for ECG, blood pressure etc

**RECALL NUMBER**

Z-691-7

**CODE**

Version 4A software, installed in Solar 7000/8000 Patient Monitors used with Solar ECG/12SL Modules

**MANUFACTURER**

Marquette Electronics, Inc., Milwaukee, WI

**REASON**

A software defect is causing incorrect waveform data.

**PRODUCT**

Precision Medical Flowmeters, used to provide a metered dose of oxygen to patients in the hospital environment: (a) Product Number 2MFA1008; (b) Product Number 2MFA1008C; (c) Product Number 2MFA1008PTO; (d) Product No. D2MFA1008; (e) Product Number D2MFA1008C; (f) Product Number Y2MFA1008; (g) Product Number Y2MFA1008C

**RECALL NUMBER**

Z-698/704-7

## **FDA CLASS II AND III RECALLS (CONT.)**

### **CODE (CONT.)**

Date codes from 395 to 397

### **MANUFACTURER**

Precision Medical, Northampton, PA

### **REASON**

The devices may catch on fire during use in high flow situations (10LPM and greater) when mounted to hospital Puritan-Bennett wall outlets.

### **PRODUCT**

Microaire Pulse Lavage Tube Sets and Pulse Lavage Hip Sets, used with the Pulse Lavage Handpiece 4740-000, a precision instrument for debriding bone surfaces as well as cleansing trauma and other soft tissue wounds

### **RECALL NUMBER**

Z-705/708-7

### **CODE**

| Product Number | Lot Number |
|----------------|------------|
|----------------|------------|

|              |           |
|--------------|-----------|
| (a) 4740-060 | 129624156 |
|--------------|-----------|

|          |           |
|----------|-----------|
| 4740-060 | 019724464 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-060 | 029725355 |
|----------|-----------|

|              |           |
|--------------|-----------|
| (b) 4740-061 | 119623581 |
|--------------|-----------|

|          |           |
|----------|-----------|
| 4740-061 | 119623582 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-061 | 119623583 |
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|          |           |
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| 4740-061 | 019724833 |
|----------|-----------|

|          |           |
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| 4740-061 | 029724834 |
|----------|-----------|

|          |                      |
|----------|----------------------|
| 4740-061 | 029725487, 039725776 |
|----------|----------------------|

|              |           |
|--------------|-----------|
| (c) 4740-062 | 119623858 |
|--------------|-----------|

|          |           |
|----------|-----------|
| 4740-062 | 129623048 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-062 | 129624155 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-062 | 129624395 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-062 | 019724465 |
|----------|-----------|

|          |           |
|----------|-----------|
| 4740-062 | 039725707 |
|----------|-----------|

(d) 5600-70 DePuy Lot Number R98AK4000 DePUY Product MicroAire Lot Number 019724466

### **MANUFACTURER**

Microaire Surgical Instruments, Charlottesville, VA

### **REASON**

The devices are subject to separation at the joint between the nose connection and the pump body of the product which could result in the nozzle falling into the surgical field.

### **PRODUCT**

Anesthesia Gas Sampling Tee Connector, Part Number 92002, and Anesthesia Circuits which contain the Gas Sampling Tee Connector: (a) Ohmeda brand Gas Sampling Straight Tee (Plastic); (b) SpaceLabs Medical brand TRU-LINK

DISPOSABLE ANESTHETIC AGENT SAMPLE LINE WITH GAS SAMPLING TEE for use with 90518 Multigas Analyzer; (c) SpaceLabs Medical brand TRU-LINK DISPOSABLE ANESTHETIC AGENT SAMPLE LINE WITH GAS SAMPLING TEE for use with 90518 Multigas Analyzer; (d) Gibeck brand Gas Sampling; (e) Gibeck brand Gas Sampling; (f) Gibeck brand Mass Spec Straight Tee; (g) Gibeck brand Gas Sampling Tee; (h) Gibeck brand Adult Anesthesia Breathing Circuit; (i) Gibeck brand Pediatric Anesthesia Breathing Circuit; (j) Gibeck brand Adult Anesthesia Breathing Circuit;

(k) Gibeck brand Gas Sampling Tee with Luer; (l) Gibeck brand Pediatric Anesthesia Breathing Circuit (m) Gibeck brand Adult Anesthesia Breathing Circuit; (n) Gibeck brand Mass Spec Tee w/Cap Put Label (Criticare); (o) Gibeck brand Gas Sampling Tee and Cap Put Label (Datex)

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **RECALL NUMBER (CONT.)**

Z-711/725-7

#### **CODE**

- (a) Product Number 6027-0000-019; Lot Number M027794
- (b) Product 015-0312-00; Lot Number M027658
- (c) Product Number 015-0313-00; Lot Number M027659
- (d) Product Number 126213-BQW; Lot Number M028791
- (e) Product Number 12820, Lot Numbers M029039, P003583, and P003612
- (f) Product Number 12820B; Lot No. M027901
- (g) Product Number 12820-150, Lot Numbers M028219 and M028360
- (h) Product Number 16303-742; Lot Numbers C033964, C034071, C034157, and C034247
- (i) Product Number 16511-742; Lot Number C034073
- (j) Product Number 173232-BPG; Lot Number C033735
- (k) Product 24432; Lot Number M028809
- (l) Product 304-0002-710; Lot Numbers C034015 and C034262
- (m) Product Number 304-0001-724; Lot Numbers C034229, C034032, and C034401
- (n) Product Number 41439B001; Lot Number M027488
- (o) Product Number 73385; Lot Number M028990

#### **MANUFACTURER**

Gibeck, Inc., Indianapolis, IN

#### **REASON**

The gas sampling tee connector was observed to be partially occluded by a thin molded membrane inside the connector.

### **PRODUCT**

Coleman Aspiration Needles, used for tissue removal: (a) Catalog Number COL-ASPI, Coleman Aspiration Needle;  
(b) Catalog Number COL-ASPB, Coleman Body Aspiration Needle

### **RECALL NUMBER**

Z-749/750-7

#### **CODE**

All units

#### **MANUFACTURER**

Kolster Methods, Inc., Anaheim, CA

#### **RECALLED BY**

Byron Medical, Tucson, AZ

#### **REASON**

The cannula tip may separate from the cannula shaft during use.

## **UPDATE**

### **RECALL NUMBER**

Z-452/453-7, Sonoline Prima and Versa Pro Ultrasound Systems with Enhanced OB Calculation Package Option, which appeared in the 7 May 1997 Enforcement Report has been extended to include the firm's issuance of a second letter alerting users of additional software errors (erroneous onscreen growth curve information)



## **FDA CLASS II AND III RECALLS (CONT.)**

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### **FDA CLASS III RECALLS**

**A class III recall is a situation in which the use of, or exposure to a violative product is not likely to cause adverse health consequences.**

**PRODUCT**

Guiatuss AC, in 1 gallon, 16 ounce, 8 ounce and 4 ounce bottles, an expectorant cough suppressant

**RECALL NUMBER**

D-214-7

**CODE**

Lot numbers: QN6718, QN6719, QS6885, QB7075

**MANUFACTURER**

Alpharma, U.S. Pharmaceutical Division, Baltimore, MD

**REASON**

Presence of precipitate.

**PRODUCT**

Enplus HD Syrup (Hydrocodone Bitartrate 2.5 mg/Phenylephrine HCl 5 mg/Chlorpheniramine Maleate 2 mg), in pint bottles, used for the relief of cough and congestion. Product is also manufactured under the names of Efasin-HD Plus Liquid and Echotuss-HC Syrup

**RECALL NUMBER**

D-215-7

**CODE**

Lot numbers: 60702 and 70108

**MANUFACTURER**

Elgee, Inc., Rosenberg, TX

**REASON**

Presence of particulate matter.

**PRODUCT**

Bumetanide Injection, USP, 0.25 mg/ml, Rx injectable diuretic

**RECALL NUMBER**

D-216-7

**CODE**

Lot Number LB224 EXP 2/99

**MANUFACTURER**

Ben Venue Laboratories, doing business as Bedford Laboratories, Bedford, OH

**REASON**

Discoloration.

**PRODUCT**

Lithobid (Lithium Carbonate extended release tablets, 300 mg, packaged in bottles of 100 and 1000, Rx used for the treatment of depression and bipolar disease)

**RECALL NUMBER**

D-217-7

**CODE**

Lot numbers: 86864 (100s) and 86848 (1000s)

**MANUFACTURER**

Solvay Pharmaceuticals, Baudett, MN

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **RECALLED BY (CONT.)**

Solvay Pharmaceuticals, Marietta, GA

### **REASON**

Dissolution failure (stability).

### **PRODUCT**

Loxitane (Loxapine Succinate) 10 mg Capsules, Rx antidepressant, in unit dose 10 (2x5) strips and bottles of 1,000, under the Lederle Laboratories label

### **RECALL NUMBER**

D-218-7

### **CODE**

Lot numbers: 445-787 and 445-788

### **MANUFACTURER**

Wyeth-Ayerst/Lederle, Pearl River, NY

### **RECALLED BY**

Wyeth-Ayerst Laboratories, Frazer, PA

### **REASON**

Superpotency.

### **PRODUCT**

Lithium Carbonate Tablets, USP, 300 mg, packaged in bottles of 100, Rx prescribed as remedial and/or maintenance drug therapy for the treatment of individuals diagnosed with manic episodes characterizing Bipolar Disorders

### **RECALL NUMBER**

D-225-7

### **CODE**

Lot Number 961458 EXP 6/1/98

### **MANUFACTURER**

Roxane Laboratories, Inc., Columbus, OH

### **REASON**

Product fails dissolution specification (stability).

### **PRODUCT**

Histalet Forte Tablets, antihistamine-decongestant (Phenylpropanolamine HCl 50 mg/Pyrimilamine Maleate 25 mg/Phenylephrine HCl 10 mg/Chlorpheniramine Maleate 4 mg), packaged in 20, 100 and 250 tablet bottles

### **RECALL NUMBER**

D-226-7

### **CODE**

Lot numbers:

F960551A - 250 tablet bottles

F960551B - 100 tablet bottles

X960778A - 20 tablet bottles \*\*

X960778B - 250 tablet bottles

X960778C - 100 tablet bottles

\*\*repackaged into bottles of 100's

### **MANUFACTURER**

Mikart, Inc., Atlanta, GA

### **QUANTITY**

Lot F960551A - 376 bottles were shipped

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **QUANTITY (CONT.)**

Lot F960551B - 3727 bottles were shipped

Lot X960778A - 9919 bottles were shipped

Lot X960778B - 259 bottles were shipped

Lot X960778C - 2160 bottles were shipped

### **REASON**

Product failed content uniformity (validation).

### **PRODUCT**

1% Lidocaine HCl Injection, USP, 10 mg/ml, 50 ml multiple dose vials held in shelf packs of 25 vials, Rx SVP for production of local or regional anesthesia

### **RECALL NUMBER**

D-227-7

### **CODE**

Lot Number 23-198-DK

### **MANUFACTURER**

Abbott Laboratories, Rocky Mount, NC

### **RECALLED BY**

Abbott Laboratories, Hospital Products Division, Abbott Park, IL

### **REASON**

Mispackaged. Correctly labeled 2% vial packaged in 1% labeled shelf pack.

### **PRODUCT**

Mexiletine Hydrochloride Capsules, 250 mg, Rx orally active antiarrhythmic used for the treatment of documented life-threatening ventricular arrhythmias, in 100 capsule bottles

### **RECALL NUMBER**

D-228-7

### **CODE**

Lots 100860A, 100861A, 101262A, 104912C

### **MANUFACTURER**

Novopharm Ltd., Toronto, Canada

### **RECALLED BY**

Novopharm USA, Inc., Schaumburg, IL

### **REASON**

Incorrect labeling. Some bottles of 250 mg capsules are labeled as containing 150 mg capsules.

### **PRODUCT**

Injectable Rx dental (local anesthetics sold in vacuum-sealed cans of 50 single use cartridges (capsule) each containing 1.8 ml solution: (a) Carbocaine 2% (36 mg) with Neo-Cobefrin 1:2000 Injection (Mepivacaine Hydrochloride Levonordefrin Injection, USP); (b) Lidocaine HCL 2% and Epinephrine 1:50,000 Injection (Lidocaine Hydrochloride and Epinephrine Injection, USP); (c) Lidocaine HCL 2% and Epinephrine 1:100,000 Injection (Lidocaine Hydrochloride and Epinephrine Injection, USP); (d) Marcaine 0.5% (9 mg) with Epinephrine 1:200,000 Injection (Bupivacaine Hydrochloride and Epinephrine Injection, USP); (Note: Product is labeled Cook-Waite (trademark) Marketed by Eastman Kodak Company, Dental Products, manufactured by Sanofi Winthrop, Inc., NY, NY)

### **RECALL NUMBER**

D-230/233-7

### **CODE**

Lot numbers: (a) C850RB EXP 2/99 and C520RA EXP 1/99; (b) C860RB EXP 2/99; (c) C545RB EXP 2/99, C565RA

## **FDA CLASS II AND III RECALLS (CONT.)**

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**RECALLED BY (CONT.)**

EXP 1/99, C570RB EXP 2/99; (d) C565RB EXP 8/99

**MANUFACTURER**

Sanofi Winthrop Pharmaceuticals, McPherson, KS (contract manufacturer)

Eastman Kodak Company, Rochester, NY

**REASON**

Product packaged in cans without vacuum to assure potency throughout labeled expiration date.

**UPDATE**

Alpharma, (Barre-National) Baltimore, MD, (OTC) Guaiatuss DAC, Syrup, cough suppressant/expectorant/nasal decongestant (Guiafenesisin, Pseudoephedrine Hydrochloride/Codeine Phosphate)

**RECALL NUMBER**

D-093-7

Enforcement Report has been extended to include the following lot numbers: RD6224, RH6363, RH6401, RJ6424, RL6629

**UPDATE**

Alpharma, (Barre-National) Baltimore, MD, Guaiatuss AC Syrup, sugar-free cough suppressant/expectorant (Guiafenesisin, Codeine Phosphate)

**RECALL NUMBER**

D-120-7 which appeared in the 5 March 1997, Enforcement Report has been extended to include the following lot numbers: RH6361, RH6360, RF6312, RF6272, RF6311, RC6126, RC6125, RC6179, RD6223, RC6178

**PRODUCT**

Confide HIV Home Test Kit - Federal Express Mailers

**RECALL NUMBER**

B-855-7

**CODE**

None

**MANUFACTURER**

Direct Access Diagnostics (DAD), Bridgewater, NJ

**REASON**

Federal Express mailer packages were incorrectly attached to a competitor firm's packaged product and distributed.

**PRODUCT**

Thrombin - JMI Topical Thrombin, 5,000 U.S. Units and 1,000 U.S. Units

**RECALL NUMBER**

B-922-7

**CODE**

Lot numbers: R114A77 (5000 US Units), R113A27, R113A28, R113A30 (1,000 US Units)

**MANUFACTURER**

GenTrac, Inc., subsidiary of Jones Medical Industries, Inc., Middleton, WI

**REASON**

Product failed 6-month stability testing for its labeled potency.

## **FDA CLASS II AND III RECALLS (CONT.)**

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**PRODUCT**

Fresh Frozen Plasma

**RECALL NUMBER**

B-1001-7

**CODE**

Unit numbers: 4416104, 4422379, 4422395, 4434783, 6740379, 6740383, 7014364, 7014369, 7014371, 7014372, 7014376, 7074039, 7188153, 7192601, 7195848, 7229463, 7247817, 7296027, 7351673, 7369616, 7376155, 7376914, 7378155, 7386207, 7389603, 7394208, 7396337, 7581829, 7591522, 7591546, 7635770, 7638517, 7638526, 7638533, 7638538, 7638756, 7648751, 7652746, 7652754, 7655203, 7655206, 7655210, 7665257

**MANUFACTURER**

NY Blood Services, also known as NY Blood Center, NY

**REASON**

Blood products contain the preservative Adsol but not labeled as containing that preservative.

### **UPDATE**

**RECALL NUMBER**

B-781/782-7, Streptokinase Kabikinase, a sterile purified preparation of bacterial protein elaborated by group C B-hemolytic streptococci, which appeared in the 4 June 1997, Enforcement Report is being updated as follows:  
(a) Streptokinase Kabikinase 250,000 IU, lot 14476A51; (b) Streptokinase Kabikinase 1,500,000IU, lot 14304A51  
Additional information from the firm indicates portions of these lots were labeled

**MANUFACTURED BY**

Kabi Pharm., Inc., Uppsala, Sweden

**PRODUCT**

MaxiCide Plus Glutaraldehyde Sterilizing and Disinfecting Solution, packaged in 1 gallon bottles

**RECALL NUMBER**

Z-642-7

**CODE**

Lot Number 7B-0037

**MANUFACTURER**

Chemrite Industries, Inc., Lannon, WI

**RECALLED BY**

Cottrell, Ltd., Englewood, CO

**REASON**

Part of the subject lot was mislabeled as MaxiCide, which contains 2.4% glutaraldehyde, rather than MaxiCide Plus, which contains 3.4% glutaraldehyde.

**PRODUCT**

Nonfiber Optic High Speed Dental Handpieces: (a) Catalog Number 750044, Tradition Non-Fiber Optic Handpiece with conventional chuck (with wrench); (b) Catalog Number 780044, Traditional L Non-fiber Optic Handpiece with Power Lever chuck (wrenchless)

**RECALL NUMBER**

Z-674/675-7

**CODE**

All with date code E127 through E227

**MANUFACTURER**

Midwest Dental Products (Dentsply), Des Plaines, IL

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **REASON (CONT.)**

Some of the hand pieces may have loose fitting water spray tubes which may fall out during use, and be swallowed or aspirated.

### **PRODUCT**

Advantage EMG System, Model A100, an electromyogram device used to measure and record electrical activity associated with skeletal muscle

### **RECALL NUMBER**

Z-687-7

### **CODE**

All serial numbers

### **MANUFACTURER**

Advantage Medical, London, Ontario, Canada

### **REASON**

The device could cause an electrical burn to the patient.

### **PRODUCT**

GDXI Anatomically Correct Lifeline Patient Cable with Leadwires, Model Number 14081 - Type A, an anatomically correct Lifeline Patient Cable to a Siemens 15 Pin Connector with lead wires, for ECG monitoring in general practitioner settings

### **RECALL NUMBER**

Z-726-7

### **CODE**

Lot numbers of the cable/lead wire: C02105CH, C02504CH, and C02505CH. NOTE: The finished device kit is NOT identified with lot numbers

### **MANUFACTURER**

Graphic Controls Corporation, Cherry Hill, NJ

### **RECALLED BY**

Graphic Controls Corporation, Buffalo, NY

### **REASON**

The lead wires were placed incorrectly into the cable, which caused the lead location to be mislabeled.

### **PRODUCT**

Stainless Steel CHS Keyed Lag Screw - Super:

(a) Part Number 1327-46-000

(b) Part Number 1327-48-000

(c) Part Number 1327-50-000

(d) Part Number 1327-52-000

(e) Part Number 1327-54-000

(f) Part Number 1327-56-000

(g) Part Number 1327-58-000

(h) Part Number 1327-60-000

(i) Part Number 1327-62-000

### **RECALL NUMBER**

Z-728/736-7

### **CODE**

Lot numbers: (a) QW235; (b) QW236, QW377; (c) QW237, QW378; (d) QW238, QW379; (e) QW239, QW478, QW519;

(f) QW240, QW381, QW479, QW529; (g) QW241, QW382, QW480; (h) QW242, QW383, QW481, QW522;

(i) QW243, QW384, QW523

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **MANUFACTURER (CONT.)**

Depuy Ace Medical Company, El Segundo, CA

### **REASON**

The 16mm head diameter screws are labeled as being 13mm head diameter screws.

### **PRODUCT**

TDx/TDxFLx Estriol Reagent Pack, List Number 9112-60, used with either Total Estriol Calibrators (lists 9112-01) or Free Estriol Calibrators (list 9118-01) in a Fluorescence Polarization Immunoassay (FPIA) in-vitro estriol or free estriol in human serum, plasma or urine

### **RECALL NUMBER**

Z-738-7

### **CODE**

Lot Numbers 22109Q100, 23635Q100, 25589Q100, and 26075Q100

### **MANUFACTURER**

Abbott Health Products, Inc., Barceloneta, Puerto Rico

### **RECALLED BY**

Abbott Laboratories, Diagnostics Division, Abbott Park, IL

### **REASON**

Storage of the antibody S reagent for extended time at elevated temperatures can cause heat stressing which results in depressed millipolarization values and display of the printed error code "PO Too Small" during calibration.

### **PRODUCT**

Quidel QuickVue Chlamydia Test, Catalog Number B006

### **RECALL NUMBER**

Z-739-7

### **CODE**

Lot Numbers B006 J04501, B006 J04801, B006, J04802, B006 J06901, B006 J08001, B006 J09001, B006 J10601, and B006 J11201

### **MANUFACTURER**

Quidel Corporation, San Diego, CA

### **REASON**

Faint or no results are obtained with the positive control solution.

### **PRODUCT**

Cathcor Remote 20 Inch Monitor, used with Siemens Cathcor System, an ECG recording device

### **RECALL NUMBER**

Z-740-7

### **CODE**

Part numbers 61-61-942 and 08-99-019, all units

## **FDA CLASS II AND III RECALLS (CONT.)**

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### **MANUFACTURER (CONT.)**

Siemens-Elma AB, Life Support Systems Division, Solna, Sweden

### **RECALLED BY**

Siemens Medical Systems, Inc., Danvers, MA

### **REASON**

The monitor used in a cardiac catheterization disconnected from the base pedestal and fell, causing injury.

### **PRODUCT**

Siemens 12 Lead ECG Patient Cable and Cable Kit, used with the Siemens Cathcor Equipment an ECG recording device:

(a) 12 Lead ECG Patient Cable, Part Number 0899300; (b) 12 Lead ECG Cable Kit, Part Number 0899399

### **RECALL NUMBER**

Z-741/742-7

### **CODE**

Lot Number R0823

### **MANUFACTURER**

ConMed Corporation, Utica, NY

### **RECALLED BY**

Siemens Medical Systems, Inc., Danvers, MA

### **REASON**

The indicator tabs for the Left Arm (LA) and Left Leg (LL) leads are reversed.



# **MANUFACTURERS' CLASS I, II AND III RECALLS**

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## **DRUGS, DEVICES, EQUIPMENT RECALLS/ALERTS/NOTICES**

NMLC point of contact for Drugs and Devices is Lieutenant Commander A. M. Capano, MSC, USN, Code 06, who may be reached at (301) 619-3065 or by DSN at 343-3065.

NMLC point of contact for Equipment is HMC Dowsland, USN, Code 03, who may be reached at (301) 619-7249 or by DSN at 343-7249.

### **FDA CLASS I RECALLS**

**A class I recall is a situation in which there is a reasonable probability that the use of, or exposure to a violative product will cause serious health consequences or death.**

### **FDA CLASS II RECALLS**

**A class II recall is a situation in which the use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences are remote.**

### **FDA CLASS III RECALLS**

**A class III recall is a situation in which the use of, or exposure to a violative product is not likely to cause adverse health consequences.**

In an effort to improve the dissemination of Quality Assurance (Product Recall, Suspension) information, a uniform QA message template has been developed cooperatively by NAVMEDLOGCOM, United States Army Medical Material Agency and Air Force Medical Logistics Office. The subject line for these messages will be Department of Defense Medical Materiel Quality Control (DODMMQC) Message and will include a Sequential Control Number. NAVMEDLOGCOM will continue to list our Drug Recall Number 97- at the end of Class I Recall Messages.

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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SUBJ: DOD-MMQC-97-1045/METOCLOPRAMIDE INJ/URGENT DRUG RECALL (DPSC 970026)

01. SOLOPAK IS RECALLING FOL MED MATL. REASON: INADEQUATE TESTING OF PREFILTERED MATL. DISPOSITION: IF WHOLESALER OR DISTRIBUTOR CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS AND RETURN TO PLACE OF PURCHASE FOR CREDIT. RA# IS REQUIRED. FOR FURTHER ASSISTANCE, CONTACT SOLOPAK'S CUSTOMER SERVICE AT 1-800-225-7656, OR 847-806-0080. PLACE OF PURCHASE MAY RETURN MATL TO: SOLOPAK LABS INC., 1845 TONNE RD., ELK GROVE VILLAGE, IL 60007-5125.

NSN: 6505-01-268-3738 UI: PG

NOM: METOCLOPRAMIDE INJECTION USP 5MG/ML 2ML VIAL 25 PER PACKAGE

NDC: F39769006602

MFR: SOLOPAK

LOT/SER NOS: 960456 - EXP: 04/30/98

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SUBJ: DOD-MMQC-97-1046/GENTAMYCIN INJ/URGENT DRUG RECALL (DPSC 970027)

01. SOLOPAK IS RECALLING FOL MED MATL. REASON: POTENCY. DISPOSITION: IF WHOLESALER OR DISTRIBUTOR CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS AND RETURN TO PLACE OF PURCHASE FOR CREDIT. RA# IS REQUIRED. FOR FURTHER ASSISTANCE, CONTACT SOLOPAK'S CUSTOMER SERVICE AT 1-800-225-7656, OR 847-806-0080. PLACE OF PURCHASE MAY RETURN MATL TO: SOLOPAK LABS INC., 1845 TONNE RD., ELK GROVE VILLAGE, IL 60007-5125.

NSN: 6505-01-213-9514 UI: PG

NOM: GENTAMICIN SULFATE INJ USP 40MG EQUIV/ML 2ML VIAL 25S

NDC: F39769001402

MFR: SOLOPAK

LOT/SER NOS: 951218 - EXP: 06/30/97

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SUBJ: DOD-MMQC-97-1047/SOLAR ECG 12SL MODULE/SAFETY ALERT (DPSC 970030)

01. MARQUETTE ISSUED A SAFETY ALERT F/FOL MATL. REASON: A DEVIATION IDENTIFIED W/SOLAR 7000/8000 MONITORS USING VERSION 4A SOFTWARE IN CONJUNCTION W/A SOLAR ECG 12SL MODULE. DISPO: MFR RECOMMENDS IMMEDIATE DISCONTINUANCE OF THE 12 SL FUNCTION. ACTYS BE AWARE THAT 12 LEAD ECG DATA STORED/PRINTED FROM MUSE SYSTEM MAY BE ERRONEOUS. IF 12SL FUNCTION IS NECESSARY, CONTACT YOUR ECG DEPT, TO SECURE AN ECG CART. SOLAR ECG MODULE CAN CONTINUE TO BE USED F/NORMAL ECG MONITORING MEASUREMENTS. MARQUETTE WILL FORWARD NEW REVISION OF SOFTWARE/INSTRS TO YOUR BIOMED ENGINEERING DEPT F/INSTALL. FOR ASST, CALL 800-558-5120/414-362-3473.

NSN: 6515-NS1 UI: EA

NOM: SOLAR ECG 12SL MODULE

MFR: MARQUETTE MEDICAL SYSTEMS

PART NO: 7000/8000 MONITORS USING VERSION 4A SOFTWARE IN CONJUNCTION WITH A SOLAR ECG 12SL MODULE.

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-29, DOD-MMQC-97-1048 SANDOGLOBULIN URGENT MARKET WITHDRAWAL (DPSC 970031)

01. NOVARTIS PHARM (FORMERLY SANDOZ) IS VOLUNTARILY WITHDRAWING FOL MATL. REASON: WITHDRAWAL IS IAW/FDA DOCUMENT DTD DEC 11, 1996. DISPOSITION: COMPLY W/CMD PROCEDURES F/ RETURNED GOODS. RETURN MATL TO PLACE OF PURCHASE. RETURN GOODS FORM/LABEL REQUIRED FOR CREDIT. PLACE OF PURCHASE RETURN MATL TO: BFI PHARMACEUTICAL SERVICES, NOVARTIS PHARMACEUTICALS RECALL PROGRAM/SRC, 801-N NORTH BLACKLAWN RD, CONYERS GA 30207. FOR ASST., CALL NOVARTIS CUST SVC AT 800-526-0175/201-503-8300.

NSN: 6505-01-430-8898 UI: VI  
NOM: GLOBULIN IMMUNE FOR INJECTION FREEZE-DRIED POWDER 6 GM VIAL  
NDC: F00078012496  
MFR: NOVARTIS  
LOT/SER NOS: 513Y2050 6.371.513.0

02. REASON AND DISPOSITION AS ABOVE.  
NSN: 6505-01-351-2671 UI: PG  
NOM: GLOBULIN IMMUNE FOR INJECTION POWDER FORM 6GM VIAL 10/PACKAGE  
NDC: F00078012419  
MFR: NOVARTIS  
LOT/SER NOS: 513Y2081 6.371.513.0

NOTE: LOT NO. 6.371.513.0 IS ON THE VIAL.

TRADE NAME: SANDOGLOBULIN

CLASS 1 MESSAGE DRUG RECALL NUMBER 97-29

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SUBJ: DOD-MMQC-97-1049/RECOMBINANT/RECOMBINATE/URGENT PRODUCT RECALL (DPSC 970033)

01. BAXTER HEALTHCARE CORP IS RECALLING THE FOL MATL. REASON: STERILITY. DISPOSITION: IMMEDIATELY DISCONTINUE DISTRIBUTION AND USE OF MATL. IF WHOLESALER OR DISTRIBUTOR HAS CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND, RETURN TO PLACE OF PURCHASE FOR CREDIT. RETURN GOODS AUTHORIZATION IS REQUIRED. FOR ASST., CALL BAXTER AT 1-800-423-2090 OR 847-948-2815.

NSN: 6505-NS1 UI: EA  
NOM: ANTIHEMOPHILIC FACTOR, (RECOMBINANT), RECOMBINATE, 976 IU  
NDC: F00944293803  
MFR: BAXTER HEALTHCARE CORP  
LOT/SER NOS: 2938M228AA

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS2 UI: EA  
NOM: ANTIHEMOPHILIC FACTOR, (RECOMBINANT), RECOMBINATE, 291 IU  
NDC: F00944293801  
MFR: BAXTER HEALTHCARE CORP

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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LOT/SER NOS: 2938M229AA (CONT.)

DOD-MMQC-97-1049

### 03. REASON AND DISPOSITION AS ABOVE

NSN: 6505-NS3 UI: EA

NOM: ANTIHEMOPHILIC FACTOR, (RECOMBINANT), RECOMBINATE 1130 IU

NDC: F00944293803

MFR: BAXTER HEALTHCARE CORP

LOT/SER NOS: 2938M230AA

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SUBJ: DOD-MMQC-97-1050/MEXILETINE TABLETS/URGENT DRUG RECALL (DPSC 970032)

01. NOVOPHARM IS RECALLING FOL MED MATL. REASON: INCORRECTLY LABELED. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE INSPECT STOCK FOR MATL; IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS. RETURN TO PLACE OF PURCHASE FOR CREDIT. PLACE OF PURCHASE MUST HAVE A RECALL RETURN FORM TO RETURN MATL. FOR ASSISTANCE/RECALL RETURN FORM CONTACT NOVOPHARM'S CUSTOMER SERVICE AT 800-426-0769 OR 416-291-8876. UPON RECEIPT OF YOUR RECALL RETURN FORM, A UPS-CALL TAG WILL BE ISSUED TO FACILITATE THE RETURN OF THIS MATL FOR FULL CREDIT.

NSN: 6505-01-256-6367 UI: BT

NOM: MEXILETINE HYDROCHLORIDE CAPSULES 150MG 100 CAPSULES PER BOTTLE

NDC: F55953073940

MFR: NOVOPHARM

|              |         |         |
|--------------|---------|---------|
| LOT/SER NOS: | 100860A | 100861A |
|              | 101262A | 104912A |

### 02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-01-255-9030 UI: BT

NOM: MEXILETINE HYDROCHLORIDE CAPSULES 250 MG 100 CAPS PER BOTTLE

NDC: F55953074140

MFR: NOVOPHARM

|              |         |         |
|--------------|---------|---------|
| LOT/SER NOS: | 100860A | 100861A |
|              | 101262A | 104912A |

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-30, DOD-MMQC-97-1051/SOFTWARE FOR SONOLINE PRIMA AND VERSA PRO ULTRASOUND SYSTEM/MFR SAFETY ALERT (DPSC 970013)

01. SIEMENS MEDICAL SYSTEMS, INC. HAS ISSUED A SAFETY ALERT FOR SONOLINE PRIMA AND VERSA PRO ULTRASOUND SYSTEM WITH ENHANCED OB CALCULATION PACKAGE OPTION. REASON: SOFTWARE ERROR - INCORRECTLY CALCULATES. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE INSPECT STOCK FOR MATL; IF FOUND CALL SIEMENS' MGR REGULATORY AFFAIRS AT 206-392-9180 FOR SOFTWARE UPGRADE. NEW UPGRADE SOFTWARE KITS (4.0 OR HIGHER) WILL BE SENT VIA REGISTERED MAIL. A COMPANY REP WILL CONTACT YOU TO VERIFY RECEIPT AND INSTALLATION OF THE KIT.

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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NSN: 6525-NS1 UI: EA (CONT.)  
NOM: SONOLINE PRIMA ULTRASOUND SYS W/ENHANCED OB CALCULATION PK OPT  
MFR: SIEMENS MEDICAL SYSTEMS, INC.  
LOT/SER NOS: 510K#-K946179 5118505-LH300

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6525-NS2 UI: EA  
NOM: SONOLINE VERSA PRO ULTRASOUND SYS W/ENHANCED OB CALC PK OPTION  
MFR: SIEMENS MEDICAL SYSTEMS, INC.  
LOT/SER NOS: 4396771-LH400 510K#-K945773/S3

CLASS 1 MESSAGE DRUG RECALL NUMBER 97-30

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-31, DOD-MMQC-97-1052 ANIMAL SHAPES CHILDREN'S CHEWABLE VITAMINS + IRON 100'S/URGENT PRODUCT RECALL (DPSC 970037)

01. NUTRO LABS, INC. IS VOLUNTARILY RECALLING FOL MATL. REASON: UNSAFE ELEVATED LEVELS OF LEAD. DISPOSITION: IF WHLES/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, IMMEDIATELY INSPECT STK F/MATL. IF FOUND COMPLY W/CMD PROCEDURES F/RETURN GOODS AND RETURN TO PLACE OF PURCHASE F/CREDIT. INCL LTR STATING NOM, LOT NO, QTY, ACTY NAME, AND EXACT-IN-THE-CLEAR ADRS WHERE CREDIT IS TO BE SENT. PLACE OF PURCHASE MAY RETURN MATL TO: MAJOR PHARM, 31778 ENTERPRISE DR, LIVONIA, MI 48150. FOR ASST., CONTACT MAJOR PHARM, ATTN: MR. SAMIR SHAH, DIR OF REGULATORY AFFAIRS, AT 800-688-9696/317-228-8000.

NSN: 6505-NS1 UI: BT  
NOM: ANIMAL SHAPES CHILDREN'S CHEWABLE VITAMINS + IRON 100 TABS  
MFR: NUTRO LABS  
LOT/SERIAL NUMBER(S): 7C00550

NOTE: THE DISTRIBUTOR OF THE ABOVE PRODUCT IS MAJOR PHARMACEUTICALS, INC.  
CLASS 1 MESSAGE DRUG RECALL NUMBER 97-31

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SUBJ: DOD-MMQC-97-1053 PULSE LAVAGE TUBE SETS AND HIP SETS/RECALL/ALERT (DPSC: 970035)

01. MICROAIRE IS RECALLING THE FOL MED MATL. REASON: THE DEVICES MAY SEPARATE AT THE JOINT BETWEEN NOSE CONNECTION AND PUMP BODY. DISPOSITION: IF WHLSE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK F/MATL. IF FOUND, RETURN TO PLACE OF PURCHASE F/CREDIT. COMPLY W/CMD PROCEDURES FOR RETURN GOODS. FOR RETURN AUTHORIZATION/ASSISTANCE, CALL MR. KIRK TRACY AT 800-538-5561, X337/804-975-8337 OR CUST SVC. AT: 800-722-0822.

NSN: 6515-01-320-9239 UI: PG  
NOM: TUBING-NOZZLE SET LAVAGE GENERAL PURPOSE STERILE DISPOSABLE 6S  
MFR: MICROAIRE SURGICAL  
DISTRIBUTOR: DEPUY  
LOT/SERIAL NUMBER(S): 129624156 019724464, 029725355

02. REASON AND DISPOSITION AS ABOVE.

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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NSN: 6515-01-320-9249                      UI: PG (CONT.)  
NOM: TUBING & NOZZLE KIT HIP JOINT IRRIGATION 5 COMP STERILE DISP 6S  
MFR: MICROAIRE SURGICAL  
DISTRIBUTOR: DEPUY

DOD-MMQC-97-1053

LOT/SERIAL NUMBER(S):  
119623581                      119623582  
119623583                      029724834  
029725487                      039725776

03. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS1                      UI: PG  
NOM: PULSE LAVAGE TUBE SETS AND HIP SETS  
MFR: MICROAIRE SURGICAL  
DISTRIBUTOR: DEPUY  
LOT/SERIAL NUMBER(S):  
119623858                      129623048  
129624155                      129624395  
019724465                      039725707

04. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS2                      UI: PG  
NOM: PULSE LAVAGE TUBE SETS AND HIP SETS  
MFR: MICROAIRE SURGICAL  
DISTRIBUTOR: DEPUY  
LOT/SERIAL NUMBER(S): R98AK4000                      019724466

NOTE: DEPUY LOT NO. IS: R98AK4000. DEPUY PRODUCT MICROAIRE LOT NO. IS: 019724466

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SUBJ: DOD-MMQC-97-1054 CLINDAMYCIN HYDROCHLORIDE CAPSULES/URGENT DRUG RECALL (DPSC 970034)

TYPE ACTION CODE: J

01. TEVA PHARMA IS RECALLING FOL MED MATL. REASON: INCORRECTLY LABELED. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE INSPECT STOCK FOR MATL; IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS. RETURN TO PLACE OF PURCHASE F/CREDIT. FOR ASSISTANCE CONTACT CUSTOMER SERVICE 800-523-6542/215-723-5544.

NSN: 6505-00-159-4892                      UI: BT  
NOM: CLINDAMYCIN HYDROCHLORIDE CAPSULES USP EQUIVALENT TO 150MG 100S  
MFR: TEVA PHARM. USA INC  
LOT/SERIAL NUMBER(S):  
28047                      28048  
28125                      28126                      28127

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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SUBJ: DOD-MMQC-97-1055 NUMZIT LOTION/DRUG RECALL (DPSC 970044)

01. BLOCK DRUG CO. IS RECALLING THE FOL MATL. REASON: TAMPER RESISTANT CAP DOES NOT MEET MFR STANDARDS. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND COMPLY WITH CMD PROCEDURES, AND RETURN TO PLACE OF PURCHASE FOR CREDIT. INCLUDE LTR IN SHIPMENT STATING NOM, LOT NO., QTY, POC, AND EXACT-IN-THE-CLEAR ADRS WHERE CREDIT IS TO BE SENT. FOR ASST, CALL BLOCK DRUG CO. AT: 800-365-6500, EXT 6589 OR 201-434-3000, EXT 1589. PLACE OF PURCHASE RETURN MATL TO: BLOCK DRUG CO., 2149 HARBOR AVE, MEMPHIS, TN 38113. RA# IS: 59623NL.

NSN: 6505-NS1 UI: EA  
NOM: NUMZIT LOTION 0.5 OZ.  
NDC: F74684909751  
MFR: BLOCK DRUG CO.  
LOT/SERIAL NUMBER(S): 03696

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-32, DOD-MMQC-97-1056 MULTIPLE VITAMINS URGENT PRODUCT RECALL (DPSC 970052)

01. SUNDOWN IS RECALLING THE FOL MATL. REASON: UNSAFE LEVEL OF LEAD DISPOSITION: IF WHOLESALE/DIST. CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STK. FOR MATL. IF FOUND COMPLY WITH CMD PROCEDURES, AND RETURN TO PLACE OF PURCHASE FOR CREDIT. INCLUDE LTR. IN SHIPMENT STATING NOM., LOT NO., QTY., POC., AND EXACT IN THE CLEAR ADRS WHERE CREDIT IS TO BE SENT. FOR ASST., CALL SUNDOWN AT: 800-327-0908/561-241-9400, EXT 115.

NSN: 6505-NS1 UI: EA  
NOM: THERAPEUTIC M MULTIVIT PLUS MINERALS 130S  
MFR: SUNDOWN CO.  
LOT/SERIAL NUMBER(S): 55409 55666

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS2 UI: EA  
NOM: SUPER MULTIPLE VITAMIN 50 50S  
MFR: SUNDOWN CO.  
LOT/SERIAL NUMBER(S): 55594

CLASS 1 MESSAGE DRUG RECALL NUMBER 97-32

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SUBJ: DOD-MMQC-97-1057 SYNCHRON CX IBCT COLUMN KIT/PRODUCT CORRECTIVE ACTION (DPSC 970047)

01. BECKMAN HAS ISSUED A PRODUCT CORRECTIVE ACTION ON FOL MEDICAL MATL. REASON: ELEVATED CONTROL RECOVERIES AND LOT-TO-LOT VARIATION. DISPOSITION: INSPECT STK FOR MATL. IF FOUND, US AND CANADA CONTACT BECKMAN AT 800-854-3633; OTHERS CONTACT YOUR LOCAL BECKMAN REP FOR CORRECTIVE ACTION INSTRUCTIONS TO ADJUST QUALITY CONTROL VALUES.

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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DOD-MMQC-97-1057 (CONT.)

NSN: 6630-NS1      UI: EA  
NOM: SYNCHRON CX IBCT COLUMN KIT, P/N 465976  
MFR: BECKMAN  
LOT/SERIAL NUMBER(S):  
SYN-102 & HIGHER

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SUBJ: DOD-MMQC-97-1058 COLREX COMPOUND CAPSULES, 100S/DRUG RECALL (DPSC 970036)

01. NUMARK LABS IS RECALLING FOL MED MATL. REASON: FORMULA DISPOSITION: IF WHOLESALER DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE INSPECT STOCK FOR MATL; IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS. RETURN TO PLACE OF PURCHASE. INCLUDE LTR IN SHIPMENT STATING POC, PHONE NO & ADRS WHERE CREDIT/REPLACEMENT CAN BE SENT. FOR ASST/RA# CALL 800-338-8079 OR 908-417-1870. PLACE OF PURCHASE RETURN MATL TO: NUMARK LABS, 75 MAYFIELD AVE, EDISON, NJ 08837.

NSN: 6505-NS1      UI: EA  
NOM: COLREX COMPOUND CAPSULES, 100'S  
NDC: F55499084001  
MFR: MIKART, INC.  
DISTRIBUTOR: NUMARK LABS  
LOT/SERIAL NUMBER(S): 951429L

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SUBJ: DOD-MMQC-97-1059 PROTID TABS/DRUG RECALL (DPSC 970042)

01. LUNBSCO, INC. IS RECALLING THE FOL MATL. REASON: POTENTIAL UNIFORMITY VARIABILITY. DISPOSITION: IF WHOLESALER OR DISTRIBUTOR HAS CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STOCK FOR MATL. IF FOUND, RETURN TO PLACE OF PURCHASE FOR CREDIT. COMPLY WITH CMD PROCEDURES FOR RETURN GOODS. PLACE OF PURCHASE RETURN MATL TO: LUNSCO, RT 2, BOX 62, PULASKI, VA 24301. FOR ASST. CALL ROCKY LUNSFORD AT 800-624-8614/540-980-4358.

NSN: 6505-NS1      UI: EA  
NOM: PROTID TABLETS, 100S  
NDC: F10892012710  
MFR: LUNBSCO, INC.  
LOT/SERIAL NUMBER(S): D960390B

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SUBJ: DOD-MMQC-97-1060 BACLOFEN TABLETS/URGENT DRUG RECALL (DPSC 970051)

01. TEVA PHARMA IS RECALLING THE FOL MATL. REASON: STABILITY. DISPOSITION: IMMEDIATELY DISCONTINUE DISTRIBUTION AND USE OF MATL. IF WHOLESALER OR DISTRIBUTOR HAS CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND, RETURN TO PLACE OF PURCHASE FOR CREDIT. RETURN GOODS AUTHORIZATION IS REQUIRED. FOR ASST. CALL 1-800-523-6542 OR 215-256-8400.



## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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NSN: 6505-01-062-5756      UI: BT (CONT.)  
NOM: BACLOFEN TABLETS 10MG, 100S  
NDC: F00332223409

DOD-MMQC-97-1060

MFR: BIOCRAFT LABS, INC.  
DISTRIBUTOR: TEVA PHARMACEUTICALS USA, INC.  
LOT/SERIAL NUMBER(S):

|       |       |
|-------|-------|
| 24061 | 24971 |
| 26467 | 24382 |
| 26356 | 26468 |
| 24383 | 26357 |
| 26469 | 26051 |
| 26358 | 26470 |
| 24970 |       |

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-01-150-4970      UI: BT  
NOM: BACLOFEN TABLETS 20MG, 100S  
NDC: F00332223609  
MFR: BIOCRAFT LABS, INC.  
DISTRIBUTOR: TEVA PHARMACEUTICALS USA, INC.  
LOT/SERIAL NUMBER(S):

|       |       |
|-------|-------|
| 24059 | 24384 |
| 24385 | 24964 |
| 24972 | 24973 |
| 26354 | 26355 |
| 26353 |       |

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SUBJ: DOD-MMQC-97-1061 HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABS/DRUG RECALL (DPSC 970050)

01. MALLINCKRODT IS RECALLING FOL MED MAT. REASON: DISCOLORATION. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL; IF FOUND RETURN TO PLACE OF PURCHASE F/CREDIT. COMPLY W/CMD PROCEDURES F/RETURN GOODS. INCL LTR IN SHIPMENT STATING NOMEN, LOT NO, QTY OPEN/UNOPEN BT, POC, DEA NO AND EXACT-IN-THE CLEAR ADDRESS WHERE CREDIT TO BE SENT. CALL MALLINCKRODT CUST SVC AT 800-326-8888 OR (314)539-1641 FOR ASST. PLACE OF PURCHASE RETURN MATL TO: MALLINCKRODT CHEMICAL INC, MALLINCKRODT AND 2ND STREETS, ST.LOUIS MO 63147 ATTN: MR. ART ROWE, BLDG 5.

NSN: 6505-01-287-0624      UI: BT  
NOM: HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS 500 TABLETS/BT  
MFR: MALLINCKRODT  
LOT/SERIAL NUMBER(S): DR6739

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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SUBJ: DOD-MMQC-97-1062 VACUTAINER BRAND SERUM TUBES, PLASMA SEPARATION TUBES, BLOOD COLLECTION SETS, NEEDLE DISPOSAL CONTAINER, AND NEEDLE HOLDER (DPSC 970041)

01. BECTON DICKINSON IS RECALLING FOL MATL. REASONS: MULTIPLE. DISPOSITION: IF MFR/WHOLESALE/DIST CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND, CALL JAVID A. BASHIR, DIRECTOR QUALITY MANAGEMENT AND REGULATORY COMPLIANCE, AT 201-847-5837 FOR RETURN GOODS AUTHORIZATION FORM, LABELS, AND ASSISTANCE.

NSN: 6515-NS1      UI: BX  
NOM: VACUTAINER BRAND PLUS SERUM TUBES 13X100MM 6ML 100S  
MFR: BECTON DICKINSON  
LOT/SERIAL NUMBER(S): 6G801                      E-DATE: 12/31/97

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS2      UI: BX  
NOM: VACUTAINER BRAND PLUS PLASMA SEPARATION TUBES  
13X75MM 3ML  
MFR: BECTON DICKINSON  
LOT/SERIAL NUMBER(S): 6B516      E-DATE: 11/30/97

03. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-01-381-5013      UI: PG  
NOM: BLOOD SAMPLE COLLECTING KIT 23GAX0.75" CRS NEEDLE WINGED 200S  
MFR: NISSHO CORP.  
LOT/SERIAL NUMBER(S): 6B081                      6B091

04. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS3      UI: BX  
NOM: VACUTAINER BRAND LOK-ON NEEDLE DISPOSABLE  
CONTAINER 50S  
MFR: BECTON DICKINSON  
LOT/SERIAL NUMBER(S):  
5H602      5H603  
5J604      5J605  
5J606      5K600  
5L600      5L601  
5L602      5M600  
6AG00      6A601  
6A602      6C600  
6C601      6D602  
6D603      6E600  
6E601      6F601

05. REASON AND DISPOSITION AS ABOVE.

NSN: 6515-NS4      UI: BX  
NOM: VACUTAINER BRAND LOK-ON NEEDLE HOLDER 250S

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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MFR: BECTON DICKINSON (CONT.)

LOT/SERIAL NUMBER(S)

5M450      5M451  
5M452      5M453  
5M454      5M455  
5M456      5M457  
6A450      6A451  
6C450      6C451  
6C452

NOTE: CATALOG NUMBERS AND RESPECTIVE REASON FOLLOWS:

|                     |                          |
|---------------------|--------------------------|
| PARA 1: CAT #367819 | REASON: MISLABELING      |
| PARA 2: CAT #367960 | REASON: WRONG COMPONENT  |
| PARA 3: CAT #007253 | REASON: DEFECTIVE TUBING |
| PARA 4: CAT #366223 | REASON: DEFECTIVE DEVICE |
| PARA 5: CAT #366221 | REASON: WEAK THREAD      |

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-33, DOD-MMQC-97-1063  
ALBUMIN/PLASMA/POLYGAM/BIOLOGIC WITHDRAWAL (DPSC 970055)

01. MFR CONDUCTING WITHDRAWAL OF FOL MATL. REASON: FDA'S REVISED RECOMMENDATIONS OF DECEMBER 11, 1996. DISPOSITION: IF WHLES/DIST CONTACTED YOU, COMPLY W/INSTRS. OTHERWISE, INSPECT STK F/MATL. IF FOUND, CONUS ACTYS RETURN TO PLACE OF PURCHASE F/REPLACEMENT. PLACE OF PURCHASE RETURN MATL TO: NATIONAL NOTIFICATION CTR, 15529 STONY CREEK WAY, SUITE 103, NOBLESVILLE, IN 46060. FOR ASST. CALL PLASMA OP CUST SVC AT 800-446-8883/703-312-8703/5683. OCONUS ACTYS DESTROY MATL, SUBMIT CERTIFICATE OF DESTRUCTION TO SHEILA PORTER, AMERICAN RED CROSS NATL HQ, PLASMA OP, 1616 N. FORT MYER DR, ROSSLYN, VA 22209.

NSN: 6505-NS1      UI: PG  
NOM: ALBUMIN (HUMAN) 25% 50ML VIAL  
NDC: F52769045105  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S): 28377213AA

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS2      UI: PG  
NOM: ALBUMIN (HUMAN) 5% 250ML VIAL  
NDC: F52769045025  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S): 29247124AA      29247125AA      29247126AA

03. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS3 UI: PG  
NOM: PLASMA PROTEIN FRACTION 5% 250ML VIAL

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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NDC: F52769043025 (CONT.)  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S): 28367413AA      28367417AA

DOD-MMQC-97-1063

04. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS4 UI: PG  
NOM: PLASMA PROTEIN FRACTION 5% 500ML VIAL  
NDC: F52769043050  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S): 28367420AA

05. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS5 UI: PG  
NOM: POLYGAM SOLVENT DETERGENT 5G VIAL  
NDC: F52769047175  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S): 26205096AA      26205097AA      26205105AA

06. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS6 UI: PG  
NOM: POLYGAM SOLVENT DETERGENT 10G VIAL  
NDC: F52769047180  
MFR: BAXTER HEALTHCARE  
DISTRIBUTOR: AMERICAN RED CROSS  
LOT/SERIAL NUMBER(S):  
26205093AA      26205094AA  
26205095AA      26205098AA  
26205099AA      26205103AA  
26206107AA      26205109AA

CLASS 1 MESSAGE DRUG RECALL NUMBER 97-33

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SUBJ: DOD-MMQC-97-1064 PORTABLE VENTILATORS/FDA CLASS II RECALL (DPSC 970038)

01. NELLCOR PURITAN BENNETT IS RECALLING THE FOL MED MATL. REASON: NO ALARM AND PRESSURE RELIEF VALVE MAY STICK IN CLOSED POSITION. DISPOSITION: IF WHOLESALER OR DIST CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STOCK FOR MATL. IF FOUND, SUSPEND AND DO NOT USE. CALL NELLCOR TO SCHEDULE REPAIRS AT 800-525-8778 X4328 OR 619-929-4000.

NSN: 6530-NS1 UI: EA  
NOM: PORTABLE VENTILATOR MDL 2800

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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MFR: NELLCOR (CONT.)  
LOT/SERIAL NUMBER(S): ALL

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SUBJ: NAVMEDLOGCOM DRUG RECALL NUMBER 97-34, DOD-MMQC-97-1065 HEARTSTART BATTERY CHARGER/PRODUCT RECALL (DPSC 970048)

01. MFR HAS ISSUED A PRODUCT RECALL FOR HEARTSTART BATTERY CHARGER. REASON: SPECIFICATION REQUIREMENTS. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STOCK FOR MATL. IF FOUND RETURN TO PLACE OF PURCHASE FOR REPLACEMENT. RECALL RESPONSE FORM REQD. FOR ASSIST/RECALL RESPONSE FORM CALL 800-648-1851, X372 OR 914-297-7700. PLACE OF PURCHASE RETURN MATL TO AULT INC. 7300 BOONE AVE, MINNEAPOLIS, MN 55428.

NSN: 6515-NS1 UI: EA  
NOM: HEARTSTART BATTERY CHARGER, CATALOG NO. 902850  
MFR: LAERDAL MEDICAL CORP  
LOT/SERIAL NUMBER(S): 97182A 97212A

NOTE 1: BATTERY WILL NOT CHARGE IF THE BATTERY CHARGER IS CONNECTED TO THE BATTERY AND THEN PLUGGED INTO THE A/C MAINS, IAW THE BATTERY CHARGER OPERATING INSTRS.

NOTE 2: RECALLED CHARGERS ARE SOLD SEPARATELY OR IN CONJUNCTION WITH HEARTSTART 3000 DEFIBRILLATORS.

CLASS 1 MESSAGE DRUG RECALL NUMBER 97-34

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SUBJ: MMQC-97-1066 BENADRYL ITCH STOPPING GEL/MARKET WITHDRAWAL (DPSC 970054)

01. IN ADDITION TO REF, MFR IS WITHDRAWING FOL MED MATL. REASON: FAILURE TO MEET SPECS. DISPOSITION: IF WHOLESALE/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STOCK FOR MATL; IF FOUND COMPLY W/CMD PROCEDURES FOR RETURNED GOODS. RETURN TO PLACE OF PURCHASE FOR REPLACEMENT. FOR ASSISTANCE CONTACT WARNER LAMBERT CUST SERV 201-540-2479.

NSN: 6505-NS1 UI: TU  
NOM: BENADRYL ITCH STOPPING GEL, 4OZ, EXTRA STRENGTH/MAXIMUM STRENGTH  
NDC: F12547017160  
MFR: WARNER LAMBERT  
LOT/SERIAL NUMBER(S):  
ALL WITH THE 17160-15 AND  
EXCEPTION OF: 17165-15

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-NS2 UI: TU  
NOM: BENADRYL ITCH STOPPING GET, 4OZ, ORIGINAL/CHILD STRENGTH  
NDC: F00501320504  
MFR: WARNER LAMBERT

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

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LOT/SERIAL NUMBER(S): (CONT.)

ALL WITH THE 17160-15 AND

EXCEPTION OF: 17165-15

NOTE: REF A, PARA 2, SHOULD READ AS PARA 2 OF THIS MSG.

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SUBJ: DOD-MMQC-97-1067 ACTH/CORTICOTROPIN FOR INJ/URGENT DRUG RECALL (DPSC 970056)

01. MFR IS RECALLING FOL MEDICAL MATL. REASON: ASSAY RESULTS. DISPOSITION: IF WHLES/DIST CONTACTED YOU, COMPLY W/THEIR INSTRS. OTHERWISE, INSPECT STK FOR MATL. IF FOUND, RETURN TO PLACE OF PURCHASE F/CREDIT. COMPLY WITH CMD PROCEDURES F/RETURN GOODS. INCLUDE LTR IN SHIPMENT STATING NSN, NOM, LOT NO., QTY, POC, AND EXACT IN-THE-CLEAR ADDRESS WHERE CREDIT IS TO BE SENT. PLACE OF PURCHASE, RETURN MATL TO: PARKE-DAVIS, MUNSONHURST RD. COMPLEX, FRANKLIN, NJ, 07416. FOR ASST CALL 800-223-0432 (OPT.2), OR 973-540-4241.

NSN: 6505-00-104-5400 UI: BT

NOM: CORTICOTROPIN FOR INJECTION USP 40 USP UNITS

NDC: F00071419801

MFR: PARKE DAVIS

LOT/SERIAL NUMBER(S):

01156P E-DATE: 08/31/97 01256P E-DATE: 09/30/97

01356P E-DATE: 09/30/97

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SUBJ: DOD-MMQC-97-1068 STREPTOKINASE KABIKINASE/URGENT RECALL (DPSC 970043)

01. PHARMACIA & UPJOHN CO ARE RECALLING THE FOL MED MATL. REASON: POTENCY. DISPOSITION: IF WHOLESALER OR DIST CONTACTED YOU, COMPLY WITH THEIR INSTRS. OTHERWISE, INSPECT STKS FOR THIS MATL. IF FOUND COMPLY WITH CMD PROCEDURES FOR RETURNED GOODS. RETURN TO PLACE OF PURCHASE FOR CREDIT. FOR ASSISTANCE/RETURN AUTHORIZATION NO. CALL 800-253-8600 (EXT 3-6717) OR 616-833-4000. PLACE OF PURCHASE RET MATL TO: PHARMACIA & UPJOHN CO, ATTN: UNIT 4959-41-030, 701 MILHAM ROAD DOCK E, KALAMAZOO, MI 49001.

NSN: 6505-01-158-8002 UI: PG

NOM: STREPTOKINASE FOR INJECTION 250000IU/VIAL 10 VIALS PER PACKAGE

NDC: F00016011059

MFR: PHARMACIA & UPJOHN

LOT/SERIAL NUMBER(S): 14476A51

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

### CURRENT LIST OF CLASS I DRUG RECALL MESSAGES FOR 1997

| <u>DOD-MMQC</u> | <u>Date/Time</u> | <u>Subject</u>  | <u>NMLC<br/>Drug Recall No.</u> |
|-----------------|------------------|---|---------------------------------|
|                 | 021500ZJAN97     | Drug Recall Albuterol Sulfate Syrup   | 97-01                           |
|                 | 021200ZJAN97     | Drug Recall Bayrab (Rabies Immune Globulin  | 97-02                           |
|                 | 151200ZJAN97     | Drug Recall Cromolyn Sodium   | 97-03                           |
|                 | 211400ZJAN97     | Drug Recall Doxycycline Hyclate Capsules  | 97-04                           |
|                 | 211200ZJAN97     | Drug Recall Immune Globulin (Sandoglobulin)   | 97-05                           |
|                 | 221200ZJAN97     | Drug Recall Epinephrine Suspension  | 97-06                           |
|                 | 241200ZJAN97     | Drug Recall Albumin (Human) Buminat   | 97-07                           |
|                 | 301200ZJAN97     | Type 1 Med Device Recall, Band Tubal Occlusion  | 97-08                           |
|                 | 051500ZFEB97     | Inspect Materiel, Sponge Radiopaque 4x8 inches  | 97-09                           |
|                 | 071500ZFEB97     | Drug Recall Multistix   | 97-10                           |
|                 | 191500ZFEB97     | Drug Recall Zantac Inj  | 97-11                           |
|                 | 211500ZFEB97     | Urgent Device Notification on Ventritex Tiered<br>Therapy Cardioverter/Defibrillator (Implantable)        | 97-12                           |
|                 | 211600ZFEB97     | Product Recall on Blood Sample Collecting Kit   | 97-13                           |
|                 | 041500ZMAR97     | Suspension of Non-Conforming Medical Materiel<br>Syringe Aspirating Newborn                               | 97-14                           |
|                 | 121500ZMAR97     | Urgent Product Recall for Immune Globulin<br>Intravenous (Human)  | 97-15                           |
|                 | 011400ZAPR97     | Drug Recall for Muro 128 Ointment   | 97-16                           |
|                 | 011500ZAPR97     | Urgent Product Withdrawal for Sandoglobulin<br>Immune Globulin Intravenous (Human) IV                     | 97-17                           |
|                 | 011600ZAPR97     | Urgent Market Withdrawal for Albumin  | 97-18                           |
|                 | 011800ZAPR97     | Type II Medical Complaint for Catheter Balloon<br>Dilatation  | 97-19                           |
|                 | 111800ZAPR97     | Device Recall Clamps, Rubber Dam  | 97-20                           |
|                 | 111500ZAPR97     | Urgent Product Recall Interlink T-Connector<br>Extension Sets with Luer Slip Adapters                     | 97-21                           |
|                 | 301500ZAPR97     | Drug Recall Gentamicin Sulfate Injection  | 97-22                           |
|                 | 131500ZMAY97     | Drug Recall Thiopental Sodium for Injection   | 97-23                           |
| 97-1006         | 191800ZMAY97     | Drug Recall Bacto Leptospira Enrichment EMJH  | 97-24                           |
| 97-1008         | 281800ZMAY97     | Safety Alert Notification for Gas Sampling Straight<br>Tee Connector                                      | 97-25                           |
| 97-1002         | 051600ZJUN97     | Amendment to ASD (HA) Policy, Policy for use<br>of Hepatitis A Virus (HAV) Vaccine and Immune<br>Globulin | 97-26                           |
| 97-1038         | 071300ZJUL97     | Immune Globulin Human/Urgent Biologic Recall  | 97-27                           |
| 97-1039         | 071400ZJUL97     | Lidocaine HCL Inj 1 Percent/Drug Recall   | 97-28                           |
| 97-1040         | 171300ZJUL97     | Sandoglobulin/Urgent Market Withdrawal  | 97-29                           |
| 97-1051         | 231300ZJUL97     | Software for Sonoline Prima and Versa Pro Ultrasound<br>System/MFR Safety Alert                           | 97-30                           |
| 97-1052         | 291300ZJUL97     | Animal Shapes Children's Chewable Vitamins + Iron/<br>100's/Urgent Product Recall                         | 97-31                           |
| 97-1056         | 041300ZAUG97     | Multiple Vitamins/Urgent Product Recall   | 97-32                           |
| 97-1063         | 061300ZAUG97     | Albumin/Plasma/Polygam/Biologic Withdrawal  | 97-33                           |
| 97-1065         | 071300ZAUG97     | Heartstart Battery Charger/Product Recall   | 97-34                           |

## MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)

### CURRENT LIST OF CLASS I, II AND III DRUG RECALL MESSAGES AND DOD-MMQC DRUG RECALL NUMBERS (CONT.)

| <u>DOD-MMQC</u> | <u>Date/Time</u> | <u>Subject</u>  | <u>NMLC CLASS 1<br/>Drug Recall No.</u> |
|-----------------|------------------|---|---|
| 97-1001         | 051500ZJUN97     | Procainamide Hydrochloride Extended-Release<br>Tabs/Urgent Drug Recall                                    |   |
| 97-1002         | 051600ZJUN97     | Amendment to ASD (HA) Policy, Policy for use<br>of Hepatitis A Virus (HAV) Vaccine and Immune<br>Globulin | 97-26                                   |
| 97-1003         | 091600ZJUN97     | Disopyramide Phosphate Caps/Urgent Drug Recall  |   |
| 97-1004         | 091500ZJUN97     | Dilantin/Ketalar Drug Recall  |   |
| 97-1005         | 091800ZJUN97     | Guaifenesin and Codeine Phosphate Syrup AC & DAC<br>Urgent Drug Recall                                    |   |
| 97-1006         | 091700ZJUN97     | Leptospira Enrichment Media/Field Matl Correction   | 97-24                                   |
| 97-1007         | 091900ZJUN97     | Heparin Lock Flush Solution/Urgent Drug Recall  |   |
| 97-1008         | 111500ZJUN97     | Gas Sampling Straight Tee Connector/Safety Alert  | 97-25                                   |
| 97-1009         | 111600ZJUN97     | Epinephrine Injection, USP/Voluntary Market Withdrawal  |   |
| 97-1010         | 111700ZJUN97     | Aspirin Delayed-Release Tablets/Urgent Drug Recall  |   |
| 97-1011         | 111800ZJUN97     | Magnesium Sulfate Inj/Urgent Drug Recall  |   |
| 97-1012         | 161200ZJUN97     | Histalet Forte Tabs/Urgent Drug Recall  |   |
| 97-1013         | 161300ZJUN97     | Miltown Tablets/ Drug Recall Notice   |   |
| 97-1014         | 161400ZJUN97     | Lithobid Tablets/Drug Recall Notice   |   |
| 97-1015         | 161500ZJUN97     | Tripeleennamine HCL Tabs/Urgent Drug Recall   |   |
| 97-1016         | 161600ZJUN97     | Clindamycin Phosphate Topical Solution/Urgent Drug Recall   |   |
| 97-1017         | 161700ZJUN97     | Hemorrhoidal Prep supp/Urgent Drug Recall   |   |
| 97-1018         | 161800ZJUN 97    | Clonazepam Tabs/Urgent Drug Recall  |   |
| 97-1019         | 171900ZJUN97     | Miochol-E W/Diluent/Urgent Drug Recall  |   |
| 97-1021         | 172100ZJUN97     | Guaifenesin and Codeine Phosphate   |   |
| 97-1022         | 172022ZJUN97     | Aspirin Tablets, Enteric Coated Orange/Urgent Drug Recall   |   |
| 97-1023         | 172023ZJUN97     | Hycamtin Topotecan Hydrochloride for Inj 4 MG/ML 5S   |   |
| 97-1024         | 172024ZJUN97     | Phillips Gelcaps/Voluntary Market Withdrawal  |   |
| 97-1025         |                  | Shelf Life  |   |
| 97-1026         |                  | Shelf Life  |   |
| 97-1027         |                  | Shelf Life  |   |
| 97-1028         |                  | Shelf Life  |   |
| 97-1029         | 232110ZJUN97     | Magnacal Renal/Product Recall   |   |
| 97-1030         | 232117ZJUN97     | Doxycycline Tabs/Geneva   |   |
| 97-1031         | 232117ZJUN97     | Thiopental Sodium for Injection/Drug Recall   |   |
| 97-1032         | 232118ZJUN97     | Sink Unit, Surgical Scrub/Safety Alert/Inspection   |   |
| 97-1033         | 242116ZJUN97     | Phenylhistine Expectorant Elixir/Urgent Drug Recall   |   |
| 97-1034         | 271926ZJUN97     | Guaifenesin and Codeine Syrup/Drug Recall   |   |
| 97-1035         | 271927ZJUN97     | Lithium Carbonate Tablets/Urgent Drug Recall  |   |
| 97-1036         | 271927ZJUN97     | Loxitane Capsules/Drug Recall   |   |
| 97-1037         | 012055ZJUN97     | Clindamycin Injection/Urgent Drug Recall  |   |
| 97-1038         | 071300ZJUL97     | RHO(D) Immune Globulin Human/Urgent Biologic  | 97-27                                   |
| 97-1039         | 071400ZJUL97     | Lidocaine HCL Inj 1 Percent/Drug Recall   | 97-28                                   |
| 97-1040         | 031924ZJUL97     | Benadryl Gel/Urgent Drug Recall   |   |
| 97-1041         | 072102ZJUL97     | Nitroglycerin Tablets/Urgent Drug Recall  |   |
| 97-1042         | 092119ZJUL97     | World Wide Web Access to DOD-MMQC Messages  |   |



## **MANUFACTURERS' CLASS I, II AND III RECALLS (CONT.)**

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### **CURRENT LIST OF CLASS I, II AND III DRUG RECALL MESSAGES AND DOD-MMQC DRUG RECALL NUMBERS (CONT.)**

|         |               |   |       |
|---------|---------------|---|-------|
| 97-1043 | 102030ZJUL97  | Plague Vaccine/Drug Recall  |       |
| 97-1044 | 102030ZJUL97  | Surgikos Latex Gloves/QA Recall   |       |
| 97-1045 | 152116ZJUL97  | Metoclopramide Inj/Urgent Drug Recall   |       |
| 97-1046 | 162120ZJUL97  | Gentamycin Inj/Urgent Drug Recall   |       |
| 97-1047 | 162120ZJUL97  | Solar ECG 12SL Module/Safety Alert  |       |
| 97-1048 | 171300ZJUL97  | Sandoglobulin/Urgent Market Withdrawal  | 97-29 |
| 97-1049 | 182043ZJUL97  | Recombinant/Recombinant/Urgent Product Recall   |       |
| 97-1050 | 182044ZJUL97  | Mexiletine Tablets/Urgent Drug Recall   |       |
| 97-1051 | 231300ZJUL97  | Software for sonoline Prima and Versa Pro Ultrasound System/MFR Safety Alert  | 97-30 |
| 97-1052 | 251904ZJUL97  | Animal Shapes Children's Chewable Vitamins + Iron 100's/Urgent Product Recall   | 97-31 |
| 97-1053 | 251910ZJUL 97 | Pulse Lavage Tube Sets and Hip Sets/Recall/Alert  |       |
| 97-1054 | 251913ZJUL97  | Clindamycin Hydrochloride Capsules/Urgent Drug Recall   |       |
| 97-1055 | 301242ZJUL97  | Numzit Lotion/Drug Recall   |       |
| 97-1056 | 041300ZAUG97  | Multiple Vitamins/Urgent Recall Number  | 97-32 |
| 97-1057 | 301243ZAUG97  | Synchron CX IBCT Column Kit/Product Corrective Action   |       |
| 97-1058 | 301244ZAUG97  | Colrex Compound Capsules, 100s/Drug   |       |
| 97-1059 |               | Protid Tabs/Drug Recall   |       |
| 97-1060 |               | Baclofen Tablets/Urgent Drug Recall   |       |
| 97-1061 |               | Hydrocodone Bitartrate and Acetaminophen Tabs/Drug Recall   |       |
| 97-1062 | 311510ZAUG97  | Vacutainer Brand Serum Tubes, Plasma Separation Tubes<br>Blood Collection Sets, Needle Disposal Container, and<br>Needle Holder |       |
| 97-1063 | 061300ZAUG97  | Albumin/Plasma/Polygam/Biologic   | 97-33 |
| 97-1064 | 011939ZAUG97  | Portable Ventilators/FDA Class II Recall  |       |
| 97-1065 | 071300ZAUG97  | Heartstart Battery Charger/Product Recall   | 97-34 |
| 97-1066 | 012008ZAUG97  | Benadryl Itch Stopping Gel/Market Withdrawal  |       |
| 97-1067 | 011941ZAUG97  | Acth/Corticotropin for Inj/Urgent Drug Recall   |       |
| 97-1068 | 011941ZAUG97  | Streptokinase Kabikinase/Urgent Recall  |       |

## **DoD-FDA SHELF LIFE EXTENSION PROGRAM**

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BUMED INSTRUCTION 6710.62A MANAGEMENT AND DISPOSAL OF DATED MEDICAL AND DENTAL MATERIEL is available to assist the activities in the management of their FDA-DoD Shelf Life Extension Programs. To obtain a copy of this instruction, contact Commanding Officer, NAVICP, 5801 Tabor Avenue, Philadelphia, PA 19120-5099, or phone (215) 697-2000.

Please be advised that NMLC is now accepting nominations for testing of medical materiel of \$1000 or more. Activities are encouraged to review the expiration dates of their current inventory and nominate items that are within 18 months of expiration date for testing and extension. Please include your activity "UIC" when reporting. All nominations must include your NSN, nomenclature, lot number, original expiration date, quantity per lot number and the manufacturer. Forward nominations to the Naval Medical Logistics Command, Attn: Code 611, Etta Ingram, 521 Fraim Street, Fort Detrick, MD 21702-5015. Point of contact is Etta Ingram who can be reached at (301) 619-3085, DSN: 343-3085, 24-hour FAX: (301) 619-3087, DSN FAX: 343-3087, and E-mail: [eingram@nml10.med.navy.mil](mailto:eingram@nml10.med.navy.mil)

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### **DoD/FDA SHELF LIFE EXTENSION PROGRAM TEST RESULTS**

Test results for Projects 1997-02 was sent out by NAVMEDLOGCOM 111300Z AUG 97. Test results will no longer be printed in the NMDMB; they will be sent by message. It will be necessary for your activity to maintain a log of DoD-FDA SHELF LIFE EXTENSION MESSAGES.

If you have not received any of the Shelf Life messages or have any questions about them, contact NAVMEDLOGCOM at the above point of contact, Etta Ingram.

### **LOTS INCLUDED AND CANCELED FROM PROJECT FOR DOD/FDA SHELF LIFE EXTENSION**

Lots included and canceled from Projects 1997-16 were sent out by NAVMEDLOGCOM 111300Z AUG 97. Lots included and canceled from projects will no longer be printed in the NMDMB; they will be sent by message. It will be necessary for your activity to maintain a log of DoD-FDA SHELF LIFE EXTENSION MESSAGES.

## **REDISTRIBUTION OF EXCESS MEDICAL AND DENTAL MATERIEL**

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| <u><b>JULY 1997</b></u> |                       |                     | <u><b>12 Month Period</b></u>  |                     |
|-------------------------|-----------------------|---------------------|--|---------------------|
| <u><b>FROM</b></u>      | <u><b>TO</b></u>      | <u><b>VALUE</b></u> |  |                     |
|                         |                       |                     | August 1996  | 2,824,299           |
|                         |                       |                     | September 1996   | 901,008             |
| NAVHOSP                 | NAVMEDCLINIC          | 4,770               | October 1996   | 681,440             |
| Newport                 | Port Hueneme          |                     | November 1996  | 833,987             |
|                         |                       |                     | December 1996  | 193,383             |
| NAVHOSP                 | BRDENCLINIC           | 53,675              | January 1997   | 678,705             |
| Millington              | Washington            |                     | February 1997  | 739,815             |
|                         |                       |                     | March 1997   | 5,315,503           |
| NAVHOSP                 | NAVMEDCLINIC          | 52,607              | April 1997   | 177,528             |
| Millington              | Pearl Harbor          |                     | May 1997   | 151,314             |
|                         |                       |                     | June 1997  | 1,192,532           |
| NAVHOSP                 | 314 <sup>th</sup> MAW | 96,508              | July 1997  | 3,187,227           |
| Millington              | Little Rock           |                     |  |                     |
|                         |                       |                     | <b>TOTAL</b>   | <b>\$16,876,735</b> |
| NAVHOSP                 | NAVHOSP               | 602,334             | <p>\$ 3,187,227 worth of Excess Medical and Dental Materiel and Equipment was redistributed this month. Your continued support of this program is appreciated.</p> |                     |
| Millington              | Camp Lejeune          |                     |  |                     |
| NAVHOSP                 | NAVDENCEN             | 78,314              |  |                     |
| Millington              | Pearl Harbor          |                     |  |                     |
| NAVHOSP                 | NAVMEDCLINIC          | 52,607              |  |                     |
| Millington              | Pearl Harbor          |                     |  |                     |
| NAVHOSP                 | NAVMEDCLINIC          | 2,638               |  |                     |
| Millington              | Pearl Harbor          |                     |  |                     |
| NAVHOSP                 | NAVHOSP               | 61,103              |  |                     |
| Millington              | Pensacola             |                     |  |                     |
| NAVHOSP                 | NAVMEDCEN             | 155,000             |  |                     |
| Millington              | Portsmouth            |                     |  |                     |
| NAVHOSP                 | IHS                   | 111,168             |  |                     |
| Millington              | Fort Worth            |                     |  |                     |
| NAVHOSP                 | NAVDENCEN             | 48,506              |  |                     |
| Millington              | Norfolk               |                     |  |                     |
| NAVHOSP                 | LSD-49                | 118,823             |  |                     |
| Millington              | USS HARPERS FERRY     |                     |  |                     |
| NAVHOSP                 | I.H.S.                | 722,318             |  |                     |
| Millington              | Fort Worth            |                     |  |                     |
| NAVHOSP                 | NAVHOSP               | 828,853             |  |                     |
| Millington              | Camp Lejeune          |                     |  |                     |
| NAVHOSP                 | NAVDENCEN             | 198,003             |  |                     |
| Millington              | Bremerton             |                     |  |                     |

## CUSTOMER FEEDBACK

**WE ARE LISTENING!!** Please keep us informed of your needs and suggestions. Use this space to let us know.

MAIL TO

Commanding Officer  
Naval Medical Logistics Command  
(ATTN: Code 06)  
Fort Detrick  
Frederick, MD 21702-5015

COMMENTS:

DATE:\_\_\_\_\_

[illegible]

Attach additional sheets if necessary

Submitted by:\_\_\_\_\_

Activity: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: COMMERCIAL:\_\_\_\_\_

DSN: \_\_\_\_\_